FINAL REPORT, SUMMARY OF METHODOLOGY AND APPROACH

USP MEDICARE MODEL GUIDELINES v6.0

COOPERATIVE AGREEMENT
USP Medicare Model Guidelines Version 6.0
Award Authority: Congressional Earmark, Section 1860-D-4(b)(C)(ii) of the Medicare Prescription Drug Improvement and Modernization Act of 2003
Grant Number: 1C0CMS331232-01-00
Project/Program Title: USP 2013

Federal Project Officer: LT. Marie Manteuffel
CMS Grants Management Specialist: Linda Gmeiner
USP Principal Investigator: Angela G. Long, M.S.
Project Director: Jami S. Earnest, Pharm.D.

Submitted by the United States Pharmacopeial Convention
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Introduction

In December 2003, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) was signed into law. The United States Pharmacopeial Convention (USP) was named in Section 1860D-4(b)(3)(C)(ii) of the Act, which states:

> *MODEL GUIDELINES – The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs.*

The USP Medicare Model Guidelines – the list of categories and classes – are a science-based, voluntary standard emanating from the USP Council of Experts, with USP Board of Trustees authorization. In creating the USP Medicare Model Guidelines in 2004, USP utilized a process that relied upon highly qualified experts and enabled all interested parties to participate. The resulting Model Guidelines supported CMS' efforts to provide high quality care to beneficiaries in a cost-effective manner.

As stipulated in the law, USP is also responsible for revising the Model Guidelines on a continuous basis, based on "changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs." Thus, in subsequent years, USP and CMS have entered into Cooperative Agreements that resulted in the revisions of the Model Guidelines and related deliverables, developed through a process that included comprehensive review of available information and evidence, public outreach and input, and deliberation and approval by the USP Council of Experts.

The USP Medicare Model Guidelines were updated annually from 2004 through 2007, and then CMS moved to a tri-annual revision cycle in 2008. The current revision, USP Medicare Model Guidelines v6.0, represents incorporation of three years of new therapeutic uses and new Part D drugs in the USP Categories and Classes, during a time of rapid evolution of the healthcare system in the United States. Both the maturation of the Part D benefit and the changing philosophies of formulary management offered additional insight into this revision cycle.

The Guiding Principles of the USP revision process are fundamentally unchanged from the original principles set forth by the 2004 USP Medicare Model Guidelines Expert Committee. The USP Categories and Classes are developed utilizing contemporary scientific information and expert evaluation, and aim to strike a balance of assuring Part D beneficiary access to safe and effective drugs that they need with the flexibility that Plans need to offer an affordable and effective benefit. This balance creates the taxonomy of the USP Medicare Model Guidelines, which are distinctly different in philosophy and structure than other taxonomy systems classifying drugs solely based upon either pharmacology or therapeutics.

Another important consideration is the need for stability in the USP Medicare Model Guidelines in order to efficiently support the needs of the Part D benefit. While there are advances in patient-centered therapeutics for which formulary plans must account in their clinical programs, the overall structure of the USP Categories and Classes should remain sound and be adjusted judiciously.

In July 2013, USP entered into a Cooperative Agreement with CMS to revise the USP Medicare Model Guidelines for utilization during plan years 2015-2017 (Appendix I). The USP methodology and approach to revising the USP Medicare Model Guidelines drug categories and classes are outlined in this document, which is designed to accompany the final USP Medicare Model Guidelines v6.0.

Methodology and Approach
Task 1: Update Model Guidelines for Drug Categories and Classes

Update Categories and Classes

Summary.

The methodology for the USP Medicare Model Guidelines Version 6.0 was focused on two objectives:

1) Conducting a clinically-based review and incorporation of Part D drugs (as defined in 42 CFR 423.100[1]) approved since USP Medicare Model Guidelines v5.0, and
2) Updating the USP Categories and Classes as necessary to accommodate changes in therapeutic uses and the additions of new Part D drugs, as specified in §1860D-4(b)(3)(C)(ii) of the Social Security Act.[2]

The revision of the USP Medicare Model Guidelines encompassed several key activities detailed in the following sections. While the USP Medicare Model Guidelines were developed through an independent scientific process, collaboration with CMS allowed a better understanding of the needs of CMS, the place of the USP Medicare Model Guidelines in Medicare policy, and the technical details associated with Part D coverage.

Under the Rules and Procedures of the USP Council of Experts, the USP Therapeutic Information and Formulary Support Expert Committee (TIFS EC) was charged with the task of reviewing and revising the USP Medicare Model Guidelines. The TIFS EC developed Guiding Principles to provide consistency to the scientific review processes. The TIFS EC went through structured deliberation to create draft USP Medicare Model Guidelines v6.0, which underwent review by CMS and the USP public comment processes. The TIFS EC deliberated on the comments from the public and CMS, and created a final draft. The final draft USP MMG v6.0

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[1] 42 CFR 423.100,, *Part D drug definition:*

(1) Unless excluded under paragraph (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1860D–2(e)(4) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act.
(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act.
(iii) Insulin described in section 1927(k)(2)(C) of the Act
(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.
(v) A vaccine licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration.
(vi) Supplies that are directly associated with delivering insulin into the body, such as an inhalation chamber used to deliver the insulin through inhalation.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B); and
(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents

[2] **§1860D-4(b)(3)(C)(ii)**

(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES AND CLASSES.—

(i) IN GENERAL.—Subject to subparagraph (G), the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

(ii) MODEL GUIDELINES.—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

was reviewed and approved by formal ballot by the TIFS EC to produce the final USP Medicare Model Guideline v6.0. Detailed description of these activities is included in the sections below.

Interactions Between USP and CMS

Start-up Meeting. On April 12, 2013 USP submitted a final proposal to CMS for the approach and methodology for the revision of the USP Medicare Model Guidelines v6.0. CMS accepted that proposal on July 12, 2013 and issued a Cooperative Agreement 1C0CMS331232-01-00. As stipulated in that agreement, a start-up meeting was held through teleconference on August 20, 2013 between leadership of USP and CMS to review the approach, methodology, and expected deliverables coming from the revision process. This start-up meeting was in place of an 'annual' meeting between USP and CMS, which was the process of the previous Model Guidelines Expert Committees that underwent continual revision of the Model Guidelines.

The CMS attendees included:

- Jeff Kelman, M.D., Chief Medical Officer; Centers for Medicare and Medicaid Services (HHS/CMS/OA/CM)
- Cynthia Tudor, Acting Deputy Center Director, Center for Medicare (DHHS/CMS/OA/CM/MDBG)
- Tracey McCutcheon, Acting Director, Medicare Drug Benefit and C&D Data Group (DHHS/CMS/OA/CM/MDBG)
- Christian Bauer, Director, Division of Part D Policy, Medicare Drug Benefit and C&D Data Group (DHHS/CMS/OA/CM/MDBG/DPDP)
- LT. Marie Manteuffel, Project Officer, Pharmacist, Division of Part D Policy (DHHS/CMS/OA/CM/MDBG/DPDP)
- Craig Miner, Pharmacist, Division of Part D Policy (DHHS/CMS/OA/CM/MDBG/DPDP)
- Brian Martin, Pharm.D., Pharmacist, Division of Formulary and Benefit Operations (DHHS/CMS/OA/CM/MDBG/DFBO)

The USP attendees included:

- Angela G. Long, M.S., Senior Vice President, Global Alliances and Organizational Affairs
- Shawn C. Becker, M.S., R.N., Senior Director, Healthcare Quality Standards;
- Jami S. Earnest, Pharm.D., Senior Scientific Liaison, TIFS EC
- Ken Freebern, Executive Committee Manager
- Patrick Kinn, Pharmacy Intern, Healthcare Quality Standards
- Colin Vechery, Pharmacy Intern, Healthcare Quality Standards

The meeting concluded with agreement on the basic principles of USP's approaches, methodology and deliverables for the revised USP Medicare Model Guidelines, as outlined in the April proposal submitted to CMS and incorporated into the cooperative agreement.

CMS Attendance at Expert Committee Meetings. CMS Project Officer LT. Marie Manteuffel participated as the invited CMS liaison observer at the meetings of the TIFS EC, including the face-to-face meetings on July 31- August 1, 2013 and November 21, 2013. In addition, LT Teisha Robertson, Pharmacist from the Division of Formulary and Benefit Operations, attended two of the Expert Committee meetings, and presented at the face-to-face meeting on July 31, 2013.

USP-CMS Staff Meetings. CMS Project Officer LT. Marie Manteuffel was in communication with the USP staff throughout the revision process, and provided input regarding Part D eligibility of drugs, CMS policies, and other Medicare legislative considerations.

Submission of Written Materials. USP submitted a draft version of the Model Guidelines for CMS review on October 1, 2013 (Draft #3.0), November 26, 2013 (Draft #3.4), and the final draft on December 31, 2013 (Draft #4.0). Between January 1 through January 31, 2014, USP provided an open invitation to CMS to provide additional technical comments. CMS met with USP on January 29, 2014 to provide final comments. The final version of the USP Medicare Model Guidelines v6.0, an aligned CY14 Formulary Reference File—USP MMGv6.0, and the "Summary of Approach and Methodology" were delivered to CMS on February 3, 2014. These final documents incorporate an accounting for new drugs and new therapeutic uses of existing drugs, and the recommended changes resulting from updated guidance from CMS.

Therapeutic Information and Formulary Support Expert Committee (TIFS EC)

In accordance with the Rules and Procedures of the 2010-2015 USP Council of Experts, Section 6 (Appendix II), the Chairperson of the Council of Experts, Dr. Roger Williams, formed the Therapeutic Information and Formulary Support Expert Committee (Appendix III). The charge of the Expert Committee was to conduct a clinically-based review and to revise the USP Medicare Model Guidelines to incorporate Part D drugs[3] approved since USP Medicare Model Guidelines v5.0, and to update the USP Categories and Classes as necessary to accommodate changes in therapeutic uses and the additions of new Part D drugs, as specified in §1860D-4(b)(3)(C)(ii) of the Social Security Act.[4]

The individuals appointed to the Expert Committee comprised a range of expertise, including pharmacologists, clinical pharmacists, other health care practitioners, academicians, formulary specialists, providers, beneficiaries, drug information experts, healthcare policy experts, and others. Approximately one-third of the Expert Committee had been involved as previous Model Guidelines Expert Committee members, another one-third had served on a previous USP Information Expert Committee, and the remaining one-third were new volunteers to USP.

According to Section 2 of the USP Rules and Procedures, Expert Committee members serve USP as individual experts, and do not serve any outside interest. Expert Committee members shall not use their membership in any way that is, or appears to be, motivated by private gain or any outside interest. Expert Committee members must adhere to the Code of Ethics, Conflict of Interest, Disclosure and Confidentiality provisions set forth in USP Rules and Procedures. Through a formal process managed by the USP Executive Secretariat, the TIFS EC declared

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(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.
(v) A vaccine licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration.
(vi) Supplies that are directly associated with delivering insulin into the body, such as an inhalation chamber used to deliver the insulin through inhalation.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B); and
(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents

[4] **§1860D-4(b)(3)(C)(ii)**

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(ii) MODEL GUIDELINES.—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

their Conflicts of Interest and signed confidentiality forms as described in the Rules and Procedures of the USP Council of Experts (Appendix II).

Reporting of Conflict of Interest

Per the Bylaws of the USP Convention and the Rules and Procedures of the USP Council of Experts, USP Experts are required to disclose Conflicts of Interest (Appendix II). Conflicts of Interest do not bar participation in a USP Expert Committee, provided that the member timely and adequately discloses such Conflicts. At the beginning of the revision cycle, and at every live meeting, the TIFS EC members updated their Conflicts of Interest on a written disclosure form maintained with the USP Executive Secretariat. In addition, at various times in the TIFS EC meetings, members verbally disclosed Conflict of Interest and often recused themselves from discussion.

Deliberation of the Expert Committee

The Expert Committee met six (6) times during the deliberation process from July 2013 through December 2013. Their work fell into several distinct areas of deliberation:

1) Review and refinement of the USP Medicare Model Guidelines Guiding Principles, to ensure continuity of processes from previous revisions and to provide consistency within the current revision cycle (Appendix IV).

2) Independent scientific review of new Part D drugs or Part D drugs with new FDA approved indications (Appendix V). There were four main sources of input for this process:
   a. FDA actions related to new and existing drugs in the US market (new drug approvals, new labeling, removal of approval)
   b. CMS Policies and Procedures, including the CY14 Formulary Reference File
   c. Federal Medicare Legislation
   d. Clinical and scientific information related to drugs and their therapeutic use, including experience and expertise of Expert Committee members

3) Review of information provided by public comment mechanisms, including Manufacturer Consultations (Appendix VI), Open Microphone Web Meetings (Appendix VII), and written Public Comment received in response to public posting of the draft USP Medicare Model Guidelines v6.0 (Appendix VIII).

The Expert Committee utilized a consensus approach in making changes to the USP Medicare Model Guidelines, and abstentions were recorded. The deliberation of the Expert Committee concluded on December 17, 2013.

Balloting of the TIFS Expert Committee

According to the Rules and Procedures of the USP Council of Experts, the TIFS EC approved the USP Medicare Model Guidelines v6.0 by official ballot. The balloting occurred between December 17 and 29, 2013. The USP Medicare Model Guidelines were balloted on individual USP Categories to allow for the members to abstain from therapeutic areas in which they had conflict of interest. Fourteen (14) of 16 TIFS EC members voted and all USP Categories passed by majority vote. With respect to individual categories, one (1) member disapproved the ***Respiratory Tract/ Pulmonary Agents***. There was one (1) abstention in each of the following categories: ***Antineoplastics***, ***Antivirals***, ***Blood Glucose Regulators***, ***Central Nervous System Agents***, ***Hormonal Agents Suppressant-Sex Hormones***, ***Immunological Agents***, ***Ophthalmic Agents***, ***Respiratory Tract/Pulmonary Agents***.

Upon final comments from CMS on January 29, 2014, an issue identified by CMS required a change to be made to ensure consistency with Part D requirements. One USP Category, ***Respiratory Tract/Pulmonary Agents***, was adjusted requiring a second ballot process for the Expert Committee. The balloting occurred between January 29 and February 2, 2014. Twelve (12) of 16 TIFS EC members voted and the ballot passed by majority vote. There were no abstentions.

Guiding Principles of Model Guidelines Expert Committee

Building upon the fundamental concepts developed by the first and second USP Medicare Model Guidelines Expert Committees (2004-2007), the TIFS EC revised the Guiding Principles through their deliberations (Appendix IV). USP acknowledges that exceptions to the Guiding Principles have arisen in previous revisions of the USP Medicare Model Guidelines. In this revision cycle, there are no known exceptions.

Identification of New Part D Drugs and New Therapeutic Uses

USP staff utilized a comprehensive approach in identifying Part D drugs to be evaluated by the Model Guidelines Expert Committee for revision of USP Medicare Model Guidelines v6.0. The identification process included: 1) review of FDA actions since last USP Medicare Model Guidelines revision, 2) comparison of CMS Formulary Reference File (FRF) and USP Medicare Model Guidelines v5.0, and 3) review of new Medicare legislation. In cases where Part D eligibility of a particular drug was in question, CMS provided direct consultation to the Expert Committee. A total of 113 drugs were added to the USP Medicare Model Guidelines v6.0, and 12 drugs were removed (6 discontinued by manufacturer, 6 removed from CMS FRF). There were 27 new Part D eligible drugs as a result of benzodiazepines and barbiturates being included in the Medicare Part D benefit by MIPPA (16), and new entries on the CMS Formulary Reference File (11).

Table 1: Additions to the USP Medicare Model Guidelines v5.0, Creating USP Medicare Model Guidelines v6.0

New FDA-approved drugs	82
New approved FDA indications, generating a second position on the USP Medicare Model Guidelines	4
New Part D eligible drugs—CMS FRF	11
New Part D eligible drugs—MIPPA	16
TOTAL :	**113**

Review of FDA actions. USP conducted a review of FDA actions and biologic approvals between December 1, 2010 and December 17, 2013. This time frame was defined by the end of the last revision cycle, and the end of the TIFS EC deliberation period in the current revision cycle. The sources of data for the drug review included the online published actions for FDA Center for Drug Evaluation and Research (CDER) available through Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm). The data source for FDA actions related to Vaccines, Biologics, and Blood Products was the online published actions of

the FDA Center for Biologics Evaluations and Research (CBER) (http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WhatsNewforBiologics/default.htm).

FDA actions were reviewed and assessed for potential impact on the USP Model Guidelines 5.0, as defined by new FDA approval or changes in therapeutic use. Changes in therapeutic use was defined as new FDA approved indications, significant product labeling changes, or removal of drugs from the US market. An additional assessment was made to determine if drugs were Part D eligible, based on the CY14 CMS Formulary Reference File and with verification from CMS. This process yielded 82 new drug approvals and 2 drugs with new FDA indications. Six (6) drugs removed from the US market by the manufacturer, and subsequently removed from the USP MMG.

Comparison of CMS Formulary Reference File and USP Medicare Model Guidelines v5.0. The additions of new Part D eligible drugs could also arise from existing drugs that were not previously included on the Model Guidelines v5.0, but included in the CY14 FRF. To identify these drugs, USP compared the associated drug list from the USP Medicare Model Guidelines v5.0 to the CMS Formulary Reference File (FRF) at various times in the revision cycle, and identified drugs which were current on the FRF, but not assessed by the previous Model Guidelines Expert Committee. While the CMS FRF does not guarantee reimbursement through Part D, it does represent a probable universe of Part D eligible drugs, and was considered the best proxy according to CMS liaisons supporting this revision cycle. A total of 11 drugs were identified and integrated into the USP Medicare Model Guidelines v6.0 after the final integration exercise, which utilized the CMS CY2014 Formulary Reference File (7-18-2013 date version).

The data source for the FRF alignment activities were CMS-FRF spreadsheets provided by Centers for Medicare and Medicaid Service. In addition, drugs removed from the CMS- FRF from were checked against the data sources of the FDA Structured Product Labeling at DailyMed (http://dailymed.nlm.nih.gov/dailymed/about.cfm), and the Drugs@ FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/).

Review of New Medicare Legislation. Legislative changes in the Part D benefit may also affect the USP Medicare Model Guidelines Categories and Classes. On January 1, 2013 the Medicare Improvement for Patients and Providers Act came into effect (MIPPA, Section 175 of Public Law 110-275). MIPPA provides for inclusion of benzodiazepines and barbiturates in the Medicare Part D benefit. This led to the addition of 16 drugs and the creation of one new USP Class, Benzodiazepines under the USP Category Anxiolytics.

Development of Drug Information Resources to Support Expert Committee Deliberation

Drug Summary Files. To facilitate the independent Expert Committee review of candidate drugs, a Master Drug List was developed which included all new FDA approved drugs (Appendix V). For Part D eligible drugs, Drug Summary Files were developed for new drugs, new indications, and drugs with significant product labeling changes that were assessed as potentially impacting the categories or classes of the USP Medicare Model Guidelines. For drugs similar to other agents on the market, or otherwise excluded by the Guiding Principles (e.g., combination products), no Drug Summary Files were produced unless requested by the Expert Committee.

The Drug Summary Files were developed specifically for the TIFS EC focusing on key issues that would inform about placement of drugs within the existing category and class structure. The drug information included FDA regulatory information, approved FDA labeling, FDA

Established Pharmacologic Class, therapeutic monographs, and applicable CMS regulations (e.g., protected class status). As requested by the Expert Committee, specific drug class reviews were prepared. When applicable, primary peer-reviewed scientific articles and treatment guidelines were included in the Drug Summary Files. Therapeutic monographs were obtained from Facts and Comparisons Formulary Monograph Service (http://www.factsandcomparisons.com/formulary-monograph-service-loose-leaf.aspx), the American Hospital Formulary Service Drug Information (http://www.ahfsdruginformation.com/), and from the Veterans Affairs Pharmacy Benefit Management Services (http://www.pbm.va.gov/). Existing manufacturer AMCP-style dossiers were also included.

During Expert Committee meetings, drug information resources were made available to clarify additional concepts. In circumstances where immediate information was not available, the drug information consultants provided written documentation in time for the next Expert Committee deliberations.

USP Management and Personnel

As stipulated in the Cooperative Agreement, Special Terms and Conditions, USP identified and provided skilled professional personnel to support: 1) the revision of the list of categories and classes in the USP Medicare Model Guidelines to account for new drugs and new therapeutic uses of existing drugs, 2) the process of obtaining and addressing issues raised by external and internal parties, and 3) the documentation of the processes and outcomes.

USP Staff. The TIFS EC and Drug Information Staff were overseen by the following USP staff:

Roger L. Williams, M.D., USP CEO and Chair of the Council of Experts
Angela G. Long, M.S., Senior Vice President, Global Alliances and Organizational Affairs
Shawn C. Becker, M.S., R.N., Senior Director, Healthcare Quality Standards
Jami Earnest, Pharm.D. , Senior Scientific Liaison, Healthcare Quality Standards

Drug Information Support. Additional personnel contracted by USP to provide drug information support to the TIFS EC included the following:

Independent Consultants
Nadia Assadi, Pharm.D., Drug Information Consultant
Catherine Cooke, Pharm.D., Drug Information Consultant

Pharmacy Interns
Patrick Kinn, Pharm.D. and Master of Public Health Candidate (2015) , University of Iowa, College of Pharmacy
Colin Vechery, Pharm.D Candidate (2015), Duquesne University, Mylan School of Pharmacy

Address Issues

Public Comment Mechanisms

USP conducted outreach for public input into the USP Medicare Model Guidelines v6.0 through a variety of methods. Information related to each of these methods was made available through the USP public website (www.usp.org), through USP Press Releases, and direct communication with USP member organizations and other trade associations. The public comment mechanisms were designed to ensure that the Expert Committee received appropriate input

from beneficiaries, providers, drug manufacturers, healthcare plans, and other concerned stakeholders.

Stakeholder 1:1 Consultations Interested stakeholders and manufacturers were afforded the opportunity to request a one-on-one consultation with USP in order to provide information for the TIFS EC. Manufacturers were notified that an independent scientific review would be conducted prior to their consultation, and information they provided would be used to supplement that independent review. Only scientific or clinical personnel could participate in the consultation. A total of 36 Stakeholder Consultations were conducted, and the Expert Committee was provided full access to recorded consultations. Detailed notes from each consultation were reviewed by Expert Committee members, and a summary document was developed reflecting the actions of the Expert Committee (Appendix VI).

Open Microphone Web Meetings USP hosted four (4) open microphone meetings during the Public Comment Period of USP Medicare Model Guidelines v6.0. These open microphone web meetings were designed to solicit specific feedback on the structural content and organization of the USP Medicare Model Guidelines v6.0. These public meetings did not discuss health plan coverage, plan design, treatment algorithms, or specific formulary product requirements for Part D health plans. Each session included a brief review of the proposed USP Medicare Model Guidelines v6.0, a description of the Guiding Principles, and considerations for revisions. Participants were encouraged to ask questions and provide specific feedback on the proposed USP Medicare Model Guidelines v6.0. A summary of the open microphone web meetings was provided to the Expert Committee, which reviewed the content during their deliberation process (Appendix VII).

Public Comments A draft version of the USP Medicare Model Guidelines v6.0 was presented on the USP website (www.usp.org) for public comment October 1-31, 2013. A total of 76 comments were received during this period. The TIFS EC reviewed all written public comments, and deliberated on the identified public issues during the November 21, 2013 meeting. Consideration was given to each comment, based upon the Guiding Principles and that available scientific information. A summary document was prepared by the Expert Committee, reflecting their actions resulting from these comments (Appendix VII).

CMS Comments

CMS provided USP with written three times during the USP MMG revision period. On October 31, 2013, CMS provided comments on USP Medicare Model Guidelines v6.0, Draft #3 which was available for public comment from October 1-31, 2013. On December 12, 2013 CMS provided written comments to USP, regarding USP Medicare Model Guidelines v6.0, Draft #3.4. On January 30, 2014, CMS provided written comments on USP Medicare Model Guidelines v6.0, Draft #4. The comments from CMS requested changes to the draft Model Guidelines to ensure consistency with Part D requirements. USP delivered a revised USP Medicare Model Guidelines to CMS on February 3, 2014.

TIFS Expert Committee Deliberation on Public Comments

In total, the Expert Committee utilized two (2) of the six meetings in this revision cycle to deliberate on public comments including those submitted by CMS. Some of the public comments were directly related to the USP Medicare Model Guidelines v6.0 and provided additional information to the Expert Committee. Some of the comments were considered to be more appropriately addressed by the Centers for Medicare and Medicaid Services as administrator of the Medicare benefit.

Comments Directed to CMS from External Parties

As a result of the public comment process for the USP Model Guidelines v6.0, several key issues have been brought to the attention of USP that are beyond the purview of USP's cooperative agreement, and appear to be within scope for the Centers of Medicare and Medicaid Services (CMS). USP is presenting these issues to CMS in adherence to the cooperative agreement requirement to address these issues.

- A number interested parties are requesting annual revisions of the USP Medicare Model Guidelines. They express concern that the three-year revision cycle does not meet the intent of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (P.L. 108-173) statute, which calls for 'time to time' revision. There is public concern that collective CMS policies have created a substantial barrier for patients to have timely access to new drugs.
- Interested parties also are requesting that CMS produce a transparent record of drugs that potentially may fall within the Part D benefit. The public is requesting that drugs that may also be eligible for medical benefit (Part B) be clearly marked in the USP Medicare Model Guidelines
- Interested parties also are requesting that there be a clear taxonomy connecting the "categories and classes" that the HHS Secretary can designate as "protected classes" under the Patient Protection and Affordable Care Act (P.L. 111-148), Section 3307 and the "categories and classes" under by MMA 2003 (P.L. 108-173) in the USP Medicare Model Guidelines.
    - There is concern regarding the application of utilization management tools on drugs in the "protected classes".
- Interested parties are requesting that the USP Medicare Model Guideline should be tailored to fit the specific clinical needs of the Medicare population. This would include additional consideration of recommendations by American Geriatrics Society (AGS) and PQA on use of drugs in the elderly population, and the implications of the two-drug minimum application of the Model Guidelines. (USP is aware of Medicare Payment Advisory Commission research showing that the highest utilizers within Part D are more likely to be under age 65, however, and recognizes that the Part D formularies must serve a broad population.)
- Interested parties also also requesting that USP broaden and adapt the USP Medicare Model Guidelines to more appropriately serve as the national benchmark for essential prescription drug benefits under the Affordable Care Act.

Comments Directed to CMS from USP

The USP TIFS EC creates categories and classes based on scientific and clinical data derived from FDA regulatory filings for new drugs and new therapeutic uses, peer-reviewed scientific literature, and applied expert knowledge. The TIFS EC addresses issues of stakeholder perception through its stakeholder consultations and public comment processes. It is through the Expert Committee processes of integrating these two elements, under the provision of the Law, which creates the USP Medicare Model Guidelines designed specifically for the Medicare population and consistent with Medicare benefit regulations.

There is a critical data element that has not been available to support the Expert Committee decision making process—specifically, data directly related to Medicare Part D implementation and real-world patient access to medications offered through Part D formularies.

According to sound formulary principles, pharmacy and therapeutics review committees must seek and be attentive to clinical issues arising from implementation of formulary policy.[5][6][7][8] USP has not been in a position to evaluate such data directly related to implementation of the USP MMG, as the data resides within CMS and is not publicly available. USP is obligated by principle to seek data that will inform the ongoing revision of the formulary model. USP will continue dialogue with CMS, to determine the information that CMS could provide that would be helpful to the Expert Committee

Comments from USP: Interagency Communication and Stakeholder Input

As the USP MMG formulary standard is adopted for other public health uses, it is important that USP's efficient, effective, and unbiased process benefit all stakeholders affected by the model guidelines. This requires open and transparent communications between all parties—USP, CMS Part D and CCIIO-- to meet the public health need of national formulary model categories and classes. USP will seek ongoing communication with parties that are utilizing the USP Medicare Model Guidelines.

In addition, USP will continue to seek public input from patient, providers, and other stakeholders affected by the implementation of USP standards. To date, the public input on the USP Medicare Model Guidelines has been limited and focused to Part D stakeholders, as the scope of revision has been defined by Medicare Part D utilization. USP recognizes with the additional public health application of its formulary standard, namely the ACA Essential Health Benefit benchmark for prescription drugs, that additional stakeholder input will be necessary.

Summary of Revisions, USP Medicare Model Guidelines v6.0

USP Categories and Classes

Stability of USP Categories and Classes

The TIFS EC recognized the need for stability in the USP Medicare Model Guidelines in order for the efficiency of use by administrators of the Part D benefit. USP Medicare Model Guidelines v6.0 reflects a high conservation of the USP Categories and Classes represented in USP MMG v5.0. The following section outlines the changes.

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[5] AMCP Principles of a Sound Formulary System (2000), http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9280, Accessed January 6, 2014.

[6] American Society of Health System Pharmacists (ASHP) Principles of a Sound Drug Formulary (1992), http://www.ashp.org/DocLibrary/BestPractices/FormEndPrinciples.aspx, *Accessed January 6, 2014.*

[7] Medicare Modernization Act Final Guidelines-- Formularies, CMS, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/FormularyGuidance.pdf , *Accessed January 6, 2014*

[8] CMS 2011 Program Audit and Best Practices (2012), http://www.ncpanet.org/pdf/leg/feb12/2011_program_audit_findings_best_practices.pdf, *Accessed January 6, 2014*

In total, the USP Medicare Model Guidelines v6.0 has:

- 49 USP Categories
- 151 USP Classes
- 167 Unique USP Categories or Classes
- 1 newly renamed Category, 13 new or renamed Classes

Table 2: USP Medicare Model Guidelines V1.0-V6.0

	v1.0 (2005)	v2.0 (2006)	v3.0 (2007)	v 4.0 (2008)	v5.0 (2011)	V6.0 (2014)
USP Categories	41	49	50	50	50	49
USP Classes	137	117	119	119	146	151
Unique Categories and Classes*	146	133	138	138	161	167
Formulary Key Drug Types - Total	118	141	193	192	*Retired*	*Retired*

**Unique Categories and Classes is the sum of the number of USP Classes and the number of USP Categories that have no associated classes.*

Revision Summary

One (1) USP Category was removed ***Hormonal Agents, Suppressant (Sex Hormones/ Modifiers)*** due to reclassification of drugs in another existing USP Category. One (1) USP Category was renamed (***Respiratory Tract/ Pulmonary Agents***) to more accurately reflect inclusion of pulmonary treatments in the existing USP Category. Two (2) USP Classes were removed (***Hormonal Agents, Glucocorticoids/ Mineralocorticoids*** and ***Hormonal Agents, Antiandrogens***). There were seven (7) new USP Classes and six (6) nomenclature changes for USP Classes. The revisions are described in detail in this section. (See Table 3)

Table 3: Summary of Revised USP Categories and Classes in order of appearance in the USP MMG v6.0

(Text in red designates changes from USP MMG v5.0)

USP MMG v5.0	USP MMG v6.0	Revision
Anti-Addiction/ Substance Abuse Treatment Agents, Opioid Antagonists	**Anti-Addiction/ Substance Abuse Treatment Agents, Opioid Dependence Treatments**	New USP Class
	Anti-Addiction/ Substance Abuse Treatment Agents, Opioid Reversal Agents	Renamed USP Class
Antidepressants, Serotonin/Norepinephrine Reuptake Inhibitors	**Antidepressants, SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)**	Renamed USP Class
(N/A)	**Antineoplastics, Antiandrogens**	New USP Class

Antivirals, Anti-hepatitis Agents	**Antivirals, Anti-hepatitis B (HBV) Agents**	Renamed
	Antivirals, Anti-hepatitis C (HCV) Agents (NEW)	New USP Class
Antivirals, Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors	**Antivirals, Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI)**	Renamed USP Class
Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors	**Antivirals, Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTI)**	Renamed USP Class
(N/A)	**Antivirals, Anti-HIV Agents, Integrase Inhibitors (INSTI) (NEW)**	New USP Class
(N/A)	**Anxiolytics, Benzodiazepines**	New USP Class
Hormonal Agents, Stimulant/ Replacement/ Modifying (Adrenal), Glucocorticoids/ Mineralocorticoids	**Hormonal Agents, Stimulant/ Replacement/ Modifying (Adrenal), (No USP Class)**	Removal of USP Class
Hormonal Agents, Suppressant (Sex Hormones/ Modifiers), Antiandrogens	~~**Hormonal Agents, Suppressant (Sex Hormones/ Modifiers), Antiandrogens**~~	Removal of USP Category and USP Class
	Antineoplastics, Antiandrogens	New USP Class
(N/A)	**Immunological Agents, Angioedema (HAE) Agents (NEW)**	New USP Class
Respiratory Tract Agents	**Respiratory Tract/ Pulmonary Agents**	Renamed Category
(N/A)	**Respiratory Tract/ Pulmonary Agents, Cystic Fibrosis Agents**	New USP Class
Respiratory Tract Agents Bronchodilators, Phosphodiesterase Inhibitors (Xanthines)	**Respiratory Tract/ Pulmonary Agents, Phosphodiesterase Inhibitors, Airways Disease**	Renamed USP Class

Revised USP Categories

Removed USP Category/ USP Class: Hormonal Agents, Suppressant (Sex Hormones/ Modifiers), Antiandrogens

With the FDA approval of enzalutamide, the Expert Committee reviewed the current therapeutic uses of the drugs in USP MMG v5.0 ***Hormonal Agents, Suppressant (Sex Hormones/ Modifiers), Antiandrogens.*** Since the primary FDA indications for the antiandrogens enzalutamide, bicalutamide, flutamide, and nilutamide were antineoplastic in nature, the Expert

Committee determined that reclassification of these drugs into ***Antineoplastics*** was consistent with the Guiding Principles. Dutasteride and finasteride, which are FDA approved for BPH, were already represented in the USP MMGv5.0 in ***Genitourinary Agents, Benign Prostatic Hypertrophy Agents,*** and these agents did not have antineoplastic indications. The resultant revision was the removal of both the USP Category and USP Class, ***Hormonal Agents, Suppressant (Sex Hormones/ Modifiers), Antiandrogens,*** and the creation of the new ***Antineoplastics , Antiandrogens*** USP Class. This resulted in one less USP Category, and no net change in the number of USP Classes.

Renamed USP Category: Respiratory Tract/ Pulmonary Agents

The ***Respiratory Tract/ Pulmonary Agents*** renamed USP Category was revised in response to changes in therapeutic uses of covered Part D drugs, and to more accurately reflect inclusion of pulmonary treatments in the existing USP MMG v5.0 Category. This was a nomenclature change only, and did not result in any change to the number of USP Categories.

Revised USP Classes

Removed USP Class: Glucocorticoids/ Mineralocorticoids

In response to the CMS Formulary Reference File inclusion of corticotropin, the TIFS EC reviewed the current therapeutic uses of the drugs in the USP MMG v5.0 Category ***Hormonal Agents, Stimulant/ Replacement/ Modifying (Adrenal).*** They determined that maintaining a USP Category level designation would allow for an appropriate categorization for all the drugs, and subsequently removed the single USP Class that was in that Category. This resulted in a decrease in the number of USP Classes, but did not result in any net change to the unique positions within the USP Medicare Model Guidelines.

New USP Class: Opioid Dependence Treatments and Renamed USP Class: Opioid Reversal Agents

In response to comments received during the stakeholder consultations and public comment period, the Expert Committee reviewed the USP MMG v5.0 Class ***Opioid Antagonists***. Pharmacologically, naloxone and naltrexone are opioid antagonists, however buprenorphine is a partial opioid agonist. The therapeutic uses of the four agents differ between acute reversal of opioids (naloxone) and treatment of opioid dependence (naltrexone, buprenorphine, buprenorphine/naloxone). The therapeutic nature of naloxone is different between the single agent naloxone and the combination of buprenorphine/naloxone, where orally ingested naloxone is pharmacological inert and serves as an abuse deterrent for intravenous misuse. Stakeholders were also concerned that methadone did not appear on the USP Medicare Model Guidelines in the ***Anti-Addiction/ Substance Abuse Treatment*** Category, but was included in the ***Analgesics***.

The TIFS EC reviewed the therapeutic uses of this USP Class and determined that it was appropriate due to divide and rename the USP MMG v5.0 Class ***Opioid Antagonists*** into the USP MMG v6.0 Classes ***Opioid Dependence Treatments*** and ***Opioid Reversal Agents.*** Methadone was not included in the USP MMG v6.0, as CMS does not consider it to be Part D eligible for the treatment of Opioid Dependence (see Medicare Prescription Drug Benefit Manual, Chapter 6, Section 10.8). This resulted in the increase in the number of USP Classes by one, and an increase in the number of unique positions within the USP Medicare Model Guidelines.

New USP Class: Antineoplastics, Antiandrogens

In response to the FDA approval of enzalutamide, the Expert Committee reviewed the current therapeutic uses of the drugs in USP MMG v5.0 ***Hormonal Agents, Suppressant (Sex***

Hormones/ Modifiers), Antiandrogens. Since the primary FDA indications for the antiandrogens enzalutamide, bicalutamide, flutamide, and nilutamide were antineoplastic in nature, the Expert Committee determined that reclassification of these drugs into ***Antineoplastics*** was consistent with the Guiding Principles. Dutasteride and finasteride, which are FDA approved for BPH, were already represented in the USP MMGv5.0 in ***Genitourinary Agents, Benign Prostatic Hypertrophy Agents***, and these agents did not have antineoplastic indications. The resultant revision was the removal of both the USP Category and USP Class, ***Hormonal Agents, Suppressant (Sex Hormones/ Modifiers), Antiandrogens***, and the creation of the new ***Antineoplastics , Antiandrogens*** USP Class. This resulted in one less USP Category, and no net change in the number of USP Classes.

New USP Class: Anti-hepatitis C (HCV) Agents, and Renamed USP Class: Anti-hepatitis B (HBV) Agents

In response to the FDA approval of boceprevir and telaprevir, the Expert Committee reviewed the FDA labeling and current therapeutic uses of drugs in the USP MMG v5.0 ***Anti-hepatitis Agents***. The Expert Committee decided to specify between the HCV and HBV agents, per FDA labeling, splitting the previous USP Class into two more granular USP Classes, ***Anti-hepatitis C (HCV) Agents, Anti-hepatitis B (HBV) Agents.*** This resulted in a net increase of one USP Class.

New USP Class: Anti-HIV Agents, Integrase Inhibitors (INSTI)

In response to the FDA approval of dolutegravir and elvitegravir/ cobistat/ emtricitabine/ tenofovir disoproxil fumarate, the Expert Committee created a new USP Class for products containing the pharmacologically distinct ***Integrase Inhibitors (INSTI).*** In following Guiding Principles and precedence in the USP MMG Anti-HIV drug classes, combination products are included in the sample list for this USP Class. The Expert Committee included combination products that had at least one INSTI, considering that the therapeutic use of those combination products would be specific to circumstances where the INSTI was a required therapy.

New USP Class: Benzodiazepines

In response to the changes in Part D drug eligibility through the Medicare Improvement for Patients and Providers Act (MIPPA, Section 175 of Public Law 110-275) effective January 1, 2013, the Expert Committee reviewed the FDA indications and therapeutic uses of benzodiazepines and barbiturates. Within the ***Anticonvulsants*** and ***Sleep Disorder Agents*** Categories, there were established USP MMG v5.0 Classes that would appropriately accommodate these newly eligible Part D drugs. Under the ***Anxiolytic Agents***, the Expert Committee created the new USP Class ***Benzodiazepines***. While many of these agents have multiple FDA indications, the Expert Committee followed the Guiding Principles and limited placement of drugs to a minimum number of USP Classes. This led to the addition of 16 drugs to the example list and the creation of one new USP Class.

New USP Class: Angioedema (HAE) Agents

In response to the FDA approval of icatibant, the Expert Committee reviewed the USP MMG v5.0 Category Immunological Agents. Considering the FDA labeling and therapeutic use of both icatribant and C1 esterase inhibitor (human), which was included on the CY14 CMS Formulary Reference File, the Expert Committee created the new USP Class ***Angiodedema (HAE) Agents.***

New USP Class: Cystic Fibrosis Agents

In response to the FDA approval of ivacaftor, the Expert Committee reviewed the USP MMG v5.0 Category ***Respiratory Tract Agents***. Given the pulmonary FDA indication for ivacaftor, the Expert Committee created the new USP Class ***Cystic Fibrosis Agents***. In the draft presented for public comment, ivacaftor was the only drug listed in the new USP Class. Several stakeholders suggested the inclusion of all FDA approved drugs for cystic, which included two inhalation products. The Expert Committee reviewed the therapeutic uses of these agents, and following Guiding Principles and precedence in the USP MMG, created the three-drug ***Cystic Fibrosis Agents*** Class.

Renamed USP Class: SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors)

In response to the FDA approval of levomilnacipran, vilazodone, and vortioxetine, and in response to public comments related to the ***Antidepressant*** Category, the Expert Committee reviewed all the drugs in the Category. The Expert Committee considered FDA labeling, current therapeutic uses, treatment algorithms and current peer-reviewed literature. Subsequently, the Class was renamed, ***SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/ Serotonin and Norepinephrine Reuptake Inhibitors***) and several drugs (maprotiline, nefazodone and trazodone) were moved from ***Antidepressant, Others*** into the ***SSRI/SNRI*** class. The Expert Committee acknowledges that antidepressants have complex pharmacological profiles and that patients respond uniquely. However, the USP MMG is a pharmacotherapeutic-based classification system for formulary development and is designed to support pharmacy and therapeutics committees in their selection of appropriate drugs for their patient populations. In following the Guiding Principles, and examining the therapeutic literature, the Expert Committee considers this an appropriate level of classification for these drugs following the USP MMG conventions. The SSRIs/SNRIs concept is well understood by the field, and accurately represents the known active mechanism of action of these drugs.

Renamed USP Class Phosphodiesterase Inhibitors, Airways Disease

In response to the FDA approval of roflumilast, the Expert Committee reviewed the USP MMG v5.0 Class ***Bronchodilators, Phosphodiesterase Inhibitors (Xanthines)***. The Expert Committee evaluated the current pharmacology, therapeutic uses and FDA labeling for the drugs in this class. The Expert Committee considered these agents as having a similar pharmacotherapeutic grouping, and decided to rename the class rather than creating a new class. The Expert Committee acknowledges that these drugs have complex pharmacological profiles and that patients respond uniquely. However, the USP MMG is a pharmacotherapeutic-based classification system for formulary development and is designed to support pharmacy and therapeutics committees in their selection of appropriate drugs for their patient populations. In following the Guiding Principles, and examining the therapeutic literature, the Expert Committee considers this an appropriate level of classification for these drugs following the USP MMG conventions. The class was renamed as ***Phosphodiesterase Inhibitors, Airways Disease.***

Single-Drug USP Categories or Classes

In the USP Medicare Model Guidelines v6.0, there are 12 unique positions where there is only one available Part D drug. Ten (10) of these positions are retained from the USP Medicare Model Guidelines v5.0; two (2) are new in this revision cycle.

One of the new single-drug positions, ***Hormonal Agents, Stimulant/Replacement/Modifying (Sex Hormones/Modifiers), Anabolic Steroids*** , was a USP MMG v5.0 Class with two drugs. CMS removed one of the drugs from CY14 Formulary Reference File, resulting in a single-drug USP Class. The TIFS EC deliberated upon pharmacotherapeutic principles that supported the

original class designation, and decided to retain the USP Class from v5.0. The single drug in this class is available generically, and has multiple manufacturers in the US market.

The other single-drug USP Class, ***Anti-Addiction/Substance Abuse Treatment Agents, Opioid Reversal Agents***, is discussed above in the section related to new USP Classes. Naloxone was included in the USP MMG v5.0, and the TIFS Expert Committee decided that the pharmacology and therapeutic use of the drug warranted a unique placement. Naloxone is available generically and has multiple manufacturers in the US market.

Table 4: Single-Drug USP Categories and Classes
(Text in red designates new USP Categories and Classes)

USP Category	USP Class	Comment
Anti-Addiction/Substance Abuse Treatment Agents	**Opioid Reversal Agents**	New in USP v6.0
Antidementia Agents	**Antidementia Agents, Other**	Retained, USP MMG v5.0
Antidementia Agents	**N-methyl-D-aspartate (NMDA) Receptor Antagonist**	USP MMG v5.0
Antipsychotics	**Treatment-Resistant**	USP MMG v5.0
Blood Products/Modifiers/Volume Expanders	**Coagulants**	USP MMG v5.0
Hormonal Agents, Stimulant/Replacement/Modifying (Sex Hormones/Modifiers)	**Anabolic Steroids**	New in USP v6.0
Hormonal Agents, Stimulant/Replacement/Modifying (Sex Hormones/Modifiers)	**Progesterone Agonists/Antagonists**	USP MMG v5.0
Hormonal Agents, Suppressant (Adrenal)	No USP Class	USP MMG v5.0
Hormonal Agents, Suppressant (Parathyroid)	No USP Class	USP MMG v5.0
Inflammatory Bowel Disease Agents	**Sulfonamides**	USP MMG v5.0
Otic Agents	No USP Class	USP MMG v5.0
Respiratory Tract/Pulmonary Agents	**Mast Cell Stabilizers**	USP MMG v5.0

Alignment of USP Medicare Model Guidelines with CMS Formulary Reference File

After the completion of the USP Medicare Model Guidelines v6.0, the USP Categories and Classes were mapped onto the CMS CY14 Formulary Reference File (20130718). For combination products included in the USP MMG v6.0 example list, both USP Category and Class were mapped. For other combination drugs on the CMS FRF, only a USP Category was mapped, and the USP Class was designated as "No USP Class (Combination Product)". This was to allow drugs to be mapped to therapeutic areas, but designating that they do not officially fall into the USP Medicare Model Guidelines. A similar approach was taken for Part B drugs and other drugs that may not have been placed as example drugs on the USP MMG v6.0. This occasionally occurs as a result of older drugs being included in the updates to the CMS FRF. These drugs which were not evaluated by the Expert Committee are mapped to a USP Category and designated as "No USP Class", and are not included in the example list.

The combined data will reside on the USP Web site (www.usp.org) in Microsoft Excel format. The combined file is a static resource and will be updated with the next revision cycle of the USP Medicare Model Guidelines.

Erratum: Classification of Combination Product, Atripla (Efavirenz/ Emtricitabine/ Tenofovir disoproxil fumarate)

After the publication of the USP Medicare Model Guidelines v6.0 to the USP website, USP became aware of an erratum. According to USP Standard Operating Procedure PUB-4590-04, "An Erratum/Errata is content erroneously published in a USP compendia that does not accurately reflect the intended requirements of a standard as approved by the responsible Expert Committee."

In this case, a transcription error misplaced the combination product of Efavirenz/ Emtricitabine/ Tenofovir (Atripla). The will and intent of the Expert Committee was to classify Atripla in the USP Category ***Antivirals***, USP Class ***Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI).***

CMS received revised final deliverables by April 15, 2014, and revised materials were placed on the USP website by April 21, 2014.

Appendix I: Excerpts from Cooperative Agreement 1C0CMS331232-01-00

There was a single objective included in the Cooperative Agreement 1C0CMS331232-01-00 *USP Medicare Model Guidelines Version 6.0*, which included four sub-headings.

Task 1: Update Model Guidelines for Drug Categories and Classes

The recipient agreed to update the list of categories and classes in the model guidelines to reflect changes in therapeutic used of covered Part D drugs and the addition of new covered Part D drugs. The recipient agrees that CMS will have full rights and privileges with respect to this revised list and that the final product will be in the public domain.

a) Update Categories and Classes.

a. USP agreed to participate in an annual meeting with CMS to discuss the methodology for revision the model guidelines
b. USP agreed to submit a "Summary Methodology and Approach" document describing the approach and methodology for making any revisions to the list and any sources of data used in the process. The report will include a section justifying the creation of any new categories or classes, detailing why proposed single-drug classes or categories are distinct from Version 5.0 Categories and Classes.
c. USP agreed to submit complete "Revised Model Guidelines' for the Medicare Prescription Drug Benefit which incorporates all recommended changes resulting from updates to the guidance in the maintenance phase, including accounting for new drugs and new therapeutic uses of existing drugs

b) Address Issues.

a. USP agreed to address issues raised by external and internal parties as the 'Revised Model Guidelines' are developed and finalized

c) **Draft and Final Report**.

a. USP agreed that in addition to the 'Revised Model Guidelines' and 'Summary Methodology and Approach' documents described above in 1.a), USP agreed to submit a draft and final report, which fully explains and provides all details on the methodology used to develop the 'Revised Model Guidelines'.
b. USP agreed to reference criteria and "guiding principles" used to revise the list as appropriate and to describe any exceptions to the criteria.
c. USP agreed to include a report summarizing issues raided by external and internal parties as the "Revised Model Guidelines" are developed, changed and/or finalized, and also, the manner in which such issues have been incorporated in the final "Revised Model Guidelines', or the reasons why this was not feasible.
    i. USP agreed to incorporate CMS comments and requested revisions into the draft report and finalize the report
    ii. USP agreed to use the description "Change made to ensure consistency with Part D requirements" to capture CMS directed changes from the draft to final version of the Model Guidelines.

d) Recipient Statement

a. USP agreed that the model categories and classes including revisions, as well as the assignment of any drug to any category or class, that result from this agreement, is made only for the purpose of supporting Part D formulary development and does not affect other activities. USP agreed to include this disclaimer in all communications and on all publicly available documents concerning the model guidelines.

Appendix II: Excerpts from Rules and Procedures of the 2010-2015 USP Council of Experts

2. STANDARDS OF CONDUCT

2.01 Code of Ethics

Members of the Council of Experts, Expert Committees and Expert Panels shall be required to adhere to the USP Code of Ethics, copies of which are available on USP's website.

2.02 Representation

Members of the Council of Experts, and Expert Committees, serve USP as individual experts; they do not serve any outside interest. A member of the Council of Experts or an Expert Committee shall not use his or her membership in any way that is, or appears to be, motivated by private gain or any outside interest. A member of an Expert Panel may serve an outside interest provided such interest is disclosed pursuant to Section 6.05 of these Rules.

2.03 Conflict of Interest

(a) General. Pursuant to Article VIII, Section 1, of the Bylaws and the Conflict of Interest Policy in the Code of Ethics, all members of the Council of Experts and its Expert Committees ("CoE/EC Expert") shall adhere to the Conflict of Interest provisions set forth in this section. Expert Panel members are subject to the Conflict of Interest requirements contained in Section 6.05 of these Rules. As used in this section "Conflict of Interest" includes, but is not limited to, any matter in which a CoE/EC Expert has a direct financial interest or any other personal interest of any kind which would preclude or appear to preclude such individual from exercising impartial judgment or otherwise acting in the best interest of the Convention. It is the responsibility of each CoE/EC Expert to inform the USP Executive Secretariat, the Scientific Liaison(s), and/or the chairperson of a particular Expert Committee should a situation arise in which he or she has or may have a Conflict of Interest.

(b) Recusal. No CoE/EC Expert shall vote nor take part in the final discussion or deliberation of any matter in which he or she has a Conflict of Interest. An Expert Panel member may participate in deliberations or recommendations regarding matters in which he or she has a Conflict of Interest provided disclosure of a Conflict of Interest is made pursuant to Section 6.05 of these Rules.

(c) Assignment of Work. No CoE/EC Expert shall be assigned the primary responsibility to work on an issue or question in which he or she has a Conflict of Interest. He or she may, however, provide relevant scientific information and may participate in discussions regarding such issue or question; providing, however, that final discussion, deliberation and vote on such issue or question shall be conducted without such member present. Expert Panel members who have a Conflict of Interest may be assigned work on matters in which they have a Conflict of Interest provided disclosure of such Conflict of Interest is made pursuant to Section 6.05 of these Rules.

(d) Conflict of Chair. In the case where the chairperson of an Expert Committee has a Conflict of Interest, the vice chairperson will serve. If the vice chairperson also is conflicted, a designated non-conflicted member shall lead the discussions. The chairperson of an Expert Panel that has a Conflict of Interest may continue to serve in that capacity provided disclosure of such Conflict of Interest is made pursuant to Section 6.05 of these Rules.

2.04 Conflict of Interest Statements

(a) Requirement. Each member of the Council of Experts, the Expert Committees, and Expert Panels shall submit to USP a statement of all employment, professional research, organizational memberships, and other interests that could result in a Conflict of Interest. The Conflict of Interest statement shall be updated by the member as necessary to keep it current or as requested periodically by USP. Except as specified in Section 2.05 below, the information provided in Conflict of Interest statements shall be kept confidential.

(b) Failure to Submit Statement. If a member of the Council of Experts, Expert Committee, or Expert Panel fails to submit a Conflict of Interest statement, that member will not be allowed to participate in Expert Committee or Expert Panel activities until such statement is submitted.

2.05 Identification and Resolution of Conflict Issues.

(a) USP Responsibility. USP staff, together with the chairperson of an Expert Committee or Expert Panel, shall review Conflict of Interest statements on an ongoing basis to identify potential Conflicts of Interest. Where a potential Conflict of Interest arises, the chairperson and USP staff shall work with the individual, and if necessary or in the case of Conflicts of Interest involving a member of the Council of Experts, the Chair of the Council of Experts and the USP Executive Secretariat, to resolve the matter. In the case of an Expert Panel member, the chairperson and USP staff will assure any such conflicts are adequately disclosed to the Expert Panel membership. If the matter cannot be resolved, the question shall be referred to the USP Secretary for resolution. The minutes of any meeting at which a Conflict of Interest issue has been addressed shall reflect disclosure and resolution of such issue, including any recusal of a CoE/EC Expert due to conflict of interest.

(b) Expert Responsibility. Any CoE/EC Expert or member of an Expert Panel who believes or should have reason to believe that he or she may have a Conflict of Interest shall notify USP staff and the chairperson of the Expert Committee or Expert Panel, as applicable, prior to any work on or discussion of the matter in question, and such issues shall be resolved as described in Section 2.05(a) above.

2.06 Confidentiality

(a) Obligation to Maintain Confidentiality. Each CoE/EC member shall maintain the confidentiality of all information gained in the course of his or her activities as a CoE/EC Expert, and shall not use or disclose such information for any purpose, unless such information is already publicly available. In case of doubt as to whether information is deemed confidential, the information shall be treated as confidential until otherwise indicated by the USP Executive Secretariat or USP Secretary. Expert Panel members are obligated to maintain confidentiality of materials in accordance with Section 6.05(b) of these Rules.

(b) Confidentiality Agreement. Each CoE/EC Expert and Expert Panel member shall sign a confidentiality agreement reflecting the confidentiality obligations set forth in Section 2.06(a). If a CoE/EC Expert or Expert Panel member fails to submit a confidentiality agreement, that member will not be allowed to receive any confidential information or participate in the Council of Experts, Expert Committee or Expert Panel activities until such agreement is submitted.

6. EXPERT PANELS

6.01 Formation

The CoE Chairperson may form an advisory Expert Panel to provide additional expertise and perform an assigned task for a particular Expert Committee or Expert Committees. The CoE Chairperson shall appoint the members of the Expert Panel, who may be removed by the CoE Chairperson at any time. USP will seek the most qualified experts on a particular topic, and will work to assure broad and diverse membership. At least one member of the Expert Committee to which the Expert Panel reports shall be a member of the Expert Panel. Any Expert Committee member that becomes a member of an Expert Panel or participates at an Expert Panel meeting may do so only as a representative of USP. An Expert Panel will continue until its assigned task has been completed or until dissolved by the CoE Chairperson.

6.02 Chairperson, Charge and Scope

The CoE Chairperson shall appoint, and may remove at any time, the chairperson of an Expert Panel. The CoE Chairperson shall provide an Expert Panel with a specific charge, including scope of work (advisory only), deliverables, and timelines for completion of work, and dissolve such Expert Panel at the conclusion of the specified work. The task performed by the Expert Panel shall be consistent with the Expert Committee's Work Plan, unless the Expert Panel's task is deemed by the CoE Chairperson to be critical or a public health emergency.

6.03 Reporting Requirements.

The chairperson of the Expert Panel shall report on its progress as needed or as requested by the Expert Committee chairperson or the CoE Chairperson. The Expert Panel shall issue advisory recommendations to the Expert Committee upon the completion of its task, which shall be accompanied by a disclosure of Conflicts of Interest information identified under Section 6.05(a) below. Expert Panel members will strive to reach consensus on their compendial topic and are expected to complete their task within the specified timeframe, but are not required to achieve unanimity. Dissenting views of

Expert Panel members may be expressed in writing and accompany the Expert Panel's advisory recommendations to the Expert Committee.

6.04 Joint Expert Panels

A Joint Expert Panel advisory to two or more Expert Committees may be established. However, the CoE Chairperson shall designate a lead Expert Committee responsible for the oversight of such Joint Expert Panel. In selecting members of a Joint Expert Panel and appointing a Chairperson, the CoE Chairperson shall consider the advice of the chairs of each involved Expert Committee. The formation, charge and reporting for the Joint Expert Panel shall be the responsibility of the lead Expert Committee.

6.05 Conflict of Interest and Confidentiality.

(a) Conflicts. Conflicts of Interest, as defined in Section 2.03, will not be a bar to participation on an Expert Panel or in any deliberations or recommendations of the Expert Panel, including voting, provided the Expert Panel member timely and adequately discloses any Conflict of Interest as required by Sections 2.03, 2.04 and 2.05 of these Rules to other members of the Expert Panel including the chairperson.

(b) Confidentiality. Expert Panel members are not necessarily obligated to maintain confidentiality of materials obtained and issues discussed during the course of the panel's task. However, confidentiality may be required in certain instances as identified by the Expert Panel Chairperson and USP staff including, but not limited to, protecting third party confidentiality obligations, preventing the premature disclosure of a standard, or maintaining the confidentiality of proprietary, business, or trade secret information.

Appendix III:
Members of the USP Therapeutic Information and Formulary Support Expert Committee

Chair

Nancy Jo Braden, M.D.
Medical Director
Aetna National Medical Policy and
Operations Unit
Phoenix, AZ

Vice Chair

Chester B. Good, M.D., M.P.H., F.A.C.P.
Chair, Medical Advisory Panel for Pharmacy
Department of Veterans Affairs
Pittsburgh, PA

Expert Committee Members

Marialice S. Bennett, BSPharm, RPh, FAPhA
Emeritus Professor
Ohio State University
College of Pharmacy
Columbus, OH

Andrea Brassard, Ph.D., FP-C, FAANP
Senior Policy Fellow
Nursing Practice & Policy
American Nurses Association
Silver Spring, MD

Judith P. Clark, B.S.
Pharmacy Director
Mississippi Division of Medicaid
Pharmacy Bureau
Brandon, MS

Seth M. Powsner, M.D.
Professor
Yale University School of Medicine
Psychiatry & Emergency Medicine
New Haven, CT

Marcus M. Reidenberg, M.D.
Professor
Weill Cornell Medical College
Pharmacology, Medicine and Public Health
New York, NY

N. Lee Rucker, M.S.H.P.
Chairperson, Senior Advisor
National Council on Patient Information and
Education
Rockville, MD

Babette S. Edgar, Pharm.D., M.B.A.
President
Edgar Consulting Group
Reisterstown, MD

Raymond Hohl, M.D., Ph.D.
Professor
Internal Medicine and Pharmacology
University of Iowa
Iowa City, IA

Raymond C. Love, Pharm.D., BCPP, FASHP
Professor
University of Maryland School of Pharmacy
Pharmacy Practice and Science
Baltimore, MD

Robert J. Meyer, M.D.
Director, VA CTR for Translational & Regulatory Sciences
University of Virginia, School of Medicine
Charlottesville, VA

Melody Ryan, Pharm.D., M.P.H.
Associate Professor
Pharmacy Practice and Science
University of Kentucky College of Pharmacy
Lexington, KY

Joanne G. Schwartzberg, M.D.
Consultant
Accreditation Council for Graduate Medical Education
Chicago, IL

Robert L. Talbert, Pharm.D.
Professor
University of Texas School of Pharmacy
Pharmacotherapy Education & Research Center (PERC)
San Antonio, TX

J. Russell Teagarden, D.M.H., M.A.
Senior Vice President
National Organization for Rare Disorders
Medical &Scientific Affairs
Danbury, CT

Government Liaisons

William A. Hess, B.Sc.
Pharmacist
Food and Drug Administration
OC/OO/OIM/Medical Informatics Staff
Silver Spring, MD

Yiying Tsai, Pharm.D., M.P.H.
Pharmacist
Medical Informatics Staff
Food and Drug Administration
U.S. Public Health Service
Silver Spring, MD

Marie E . Manteuffel, Pharm.D., M.P.H.
Senior Assistant Pharmacist
Division of Part D Policy
U.S. Public Health Service
Centers for Medicare and Medicaid Services
Baltimore, MD

Appendix IV: Guiding Principles

Guiding Principles
USP Medicare Model Guidelines v6.0
Therapeutic Information and Formulary Support Expert Committee
November 21, 2013

- *The Therapeutic Information and Formulary Support Expert Committee retains the goal of the original Model Guidelines Expert Committee (2004) – to strike a balance of assuring beneficiary access to the safe and effective drugs that they need with the flexibility that part D sponsors need to offer an affordable and effective benefit.*

- *The USP Medicare Model Guidelines utilize pharmacotherapeutic evidence within the context of FDA approved indications to create categories and classes. The USP Medicare Model Guidelines are composed of two organizational levels—USP Categories and USP Classes—which characterize the statutory requirement for Medicare Part D plan benefit design to include drugs from each category and class.*[1,2]

- *USP Categories and USP Classes are defined as follows:*

    - *A USP Category is the broadest classification of the USP Medicare Model Guidelines, and provides a high level formulary structure designed to include all potential therapeutic agents for diseases and conditions of Part D beneficiaries.*

    - *A USP Class is a more granular classification, occurring within a specific USP Category in the USP Model Guidelines, which provides for therapeutic or pharmacologic groupings of FDA approved medications, consistent with current U.S. healthcare practices and standards of care.*

- *USP Medicare Model Guidelines v6.0 includes a list of associated drug examples that aligns with the Part D drugs reflected on the Centers for Medicare & Medicaid Services (CMS) Formulary Reference File (FRF).*

    - *Generally a drug in the associated list may appear in more than one USP Category or USP Class if there is a scientifically valid and clinically meaningful patient care issue.*

    - *Combination drugs, and specific dosage forms/formulations/delivery systems,are generally not listed but may be included in the associated list if there is a scientifically valid and clinically meaningful patient care issue.*

- *USP will advise CMS on issues it discovers during the revision process that are relevant to implementing the USP Medicare Model Guidelines.*

[1] The Law states in Section 1860D-4(b)(3)(C) that: (D) Plan design.—(i) In general.—The Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan. (ii) Use of categories and classes in formularies.—The Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.

[2] The Law states in Section 1860D-11(e)(2)(D) that (C) Inclusion of drugs in all therapeutic categories and classes.—(i) In general.—Subject to subparagraph (G), the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.(ii) Model guidelines.—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.(iii) Limitation on changes in therapeutic classification.—The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

Appendix V: Drugs Reviewed by the TIFS EC

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
1	Abiraterone acetate	Zytiga	Janssen Biotech	4/28/2011	X		ZYTIGA is a **CYP17 inhibitor** indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.	**X**	YES 20130320	oral	Part D
2	Aclidinium bromide	Tudorza Pressair	Forest Laboratories	7/23/12	X		TUDORZA PRESSAIR is an **anticholinergic** indicated for the long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema		YES 20130320	inh	Part D
3	Ado-trastuzumab emtansine	Kadcyla	Genentech	2/22/2013		X	KADCYLA is a **HER2-targeted antibody** and **microtubule inhibitor conjugate** indicated, as a single agent, for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: 1) Received prior therapy for metastatic disease, or 2) Developed disease recurrence during or within six months of completing adjuvant therapy.	**X**	YES 20130517	i.v.	Part B
4	Afatinib Dimaleate	Gilotrif	Boehringer Ingelheim	7/12/2013	X		GILOTRIF is a **kinase inhibitor** indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. Limitation of Use: Safety and efficacy of GILOTRIF have not been established in patients whose tumors have other EGFR mutations		YES 20130924	oral	Part D
5	Alogliptin	Nesina	Takeda	1/25/2013	X		NESINA is a **dipeptidyl peptidase-4 (DPP-4) inhibitor** indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus		YES 20130320	oral	Part D
6	Apixaban	Eliquis	Bristol-Meyer Squibb	12/28/2012	X		ELIQUIS is a **factor Xa inhibitor anticoagulant** indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.		YES 20130320	oral	Part D
7	Argatroban	Argatroban	multiple	6/30/2000			Argatroban is a **direct thrombin inhibitor** indicated: 1) For prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT), 2) As an anticoagulant in adult patients with or at risk of HIT undergoing percutaneous coronary intervention (PCI)		YES 20130320	i.v.	Part B

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
8	Axitinib	Inlyta	Pfizer	1/27/2012	X		INLYTA is a **kinase inhibitor** indicated for the treatment of advanced renal cell carcinoma after failure of one prior systemic therapy.		YES 20130320	oral	Part D
9	Azilsartan medoxomil	Edarbi	Takeda	2/25/2011	X		Edarbi is an **angiotensin II receptor blocker** indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Edarbi may be used either alone or in combination with other antihypertensive agents		YES 20130320	oral	Part D
10	Aztreonam inhalant solution	Cayston	Gilead Sciences	2/27/2010			CAYSTON is a **monobactam antibacterial** indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with Pseudomonas aeruginosa. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV1 <25% or >75% predicted, or patients colonized with Burkholderia cepacia.		YES 20130320	inh	Part D
11	Bazedoxifene/ conjugated estrogens	Duavee	Wyeth Pharmaceuticals	10/3/2013			DUAVEE is a combination of **conjugated estrogens** with an **estrogen agonist/antagonist** indicated for treatment of the following conditions in women with a uterus: 1) Treatment of moderate to severe vasomotor symptoms associated with menopause, 2) Prevention of postmenopausal osteoporosis		pending	oral	Part D (pending)
12	Bedaquiline	Sirturo	Janssen Pharmaceuticals	12/28/2012	X		SIRTURO is a **diarylquinoline antimycobacterial drug** indicated as part of combination therapy in adults (≥ 18 years) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve SIRTURO for use when an effective treatment regimen cannot otherwise be provided. SIRTURO is not indicated for the treatment of latent, extra-pulmonary or drug-sensitive	**X**	YES 20130517	oral	Part D
13	Belatacept	Nulojix	Bristol-Meyer Squibb	6/15/2011		X	NULOJIX is a **selective T-cell costimulation blocker** indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplant. Use in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids. Limitations of Use: Use only in patients who are EBV seropositive.) Use has not been established for the prophylaxis of organ rejection in transplanted organs other than the kidney.	**X**	YES 20130320	i.v.	Part B

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
14	Belimumab	Benlysta	GlaxoSmithKline	3/9/2011		X	BENLYSTA is a **B-lymphocyte stimulator (BLyS)-specific inhibitor** indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy. Limitations of Use: The efficacy of BENLYSTA has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. BENLYSTA has not been studied in combination with other biologics or intravenous cyclophosphamide . Use of BENLYSTA is not recommended in these situations.	**X**	YES 20130320	i.v.	Part B/ Part D
15	Boceprevir	Victrelis	Merck Sharpe Dohme	5/13/2011	X		VICTRELIS is a **hepatitis C virus (HCV) NS3/4A protease inhibitor** indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients (18 years of age or older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy, including prior null responders, partial responders, and relapsers. VICTRELIS must not be used as a monotherapy and should only be used in combination with peginterferon alfa and ribavirin. The efficacy of VICTRELIS has not been studied in patients who have previously failed therapy with a treatment regimen that includes VICTRELIS or other HCV NS3/4A protease inhibitors.	**X**	YES 20130320	oral	Part D
16	Bosutinib	Bosulif	Pfizer	9/4/2012	X		BOSULIF is a **kinase inhibitor** indicated for the treatment of adult patients with chronic, accelerated, or blast phase Ph+ chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.		YES 20130320	oral	Part D
17	Brimonidine Tartrate	Mirvaso	Galderma Labs LP	8/23/2013			MIRVASO (brimonidine) topical gel, 0.33% is an **alpha adrenergic agonist** indicated for the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older.		pending	topical	Part D (pending)
18	Brinzolamide/ Brimonidine	Simbrinza	Alcon	4/19/2013			SIMBRINZA is a fixed combination of a **carbonic anhydrase inhibitor** and an **alpha 2 adrenergic receptor agonist** indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.		YES 20130718	ophth	Part D

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
19	Budesonide/ Formoterol fumarate	Symbicort	AstraZeneca	7/21/2006			SYMBICORT is a combination product containing a **corticosteroid** and a **long-acting beta2-adrenergic agonist** indicated for: treatment of asthma in patients 12 years of age and older, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.		YES 20130718	inh	Part D
20	C1 esterase inhibitor (human)	Cinryze	Lev Pharmaceuticals	12/10/2008		X	Cinryze is a **C1 esterase inhibitor** indicated for routine prophylaxis against angioedema attacks in adolescent and adult patients with Hereditary Angioedema (HAE).		YES 20130320	i.v.	Part B/ Part D
21	Cabazitaxel	Jevtana	Sanofi Aventis US	6/17/2010	X		JEVTANA is a **microtubule inhibitor** indicated in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.		YES 20130320	i.v.	Part B
22	Cabozantinib	Cometriq	Exelixis	11/29/2012	X		COMETRIQ is a **kinase inhibitor** indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC).	**X**	YES 20130320	oral	Part D
23	Canagliflozin	Invokana	Janssen Pharmaceuticals	3/29/2013	X		INVOKANA is a **sodium-glucose co-transporter 2 (SGLT2) inhibitor** indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	**X**	YES 20130517	oral	Part D
24	Ceftaroline fosamil	Teflaro	Cerexa	10/29/2010	X		Teflaro is a **cephalosporin antibacterial** indicated for the treatment of the following infections caused by designated susceptible bacteria:1) Acute bacterial skin and skin structure infections (ABSSSI) , 2) Community-acquired bacterial pneumonia (CABP)		YES 20130320	i.v.	Part B/ Part D
25	Clobazam	Onfi	Lundbeck	10/24/2011	X		ONFI is a **benzodiazepine** indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older		YES 20130320	oral	Part D
26	Corticotropin	Acthar	Questcor	4/29/1952	X		see FDA daily med; multiple indications.		YES 20130320	i.m. s.q.	Part B/ Part D
27	Crizotinib	Xalkori	Pfizer	8/26/2011	X		XALKORI is a **kinase inhibitor** indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. This indication is based on response rate. There are no data available demonstrating improvement in patient reported outcomes or survival with XALKORI.	**X**	YES 20130320	oral	Part D

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
28	Crofelemer	Fulyzaq	Salix Pharmaceuticals	12/31/2012	X		FULYZAQ is an **anti-diarrheal** indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy	**X**	YES 20130517	oral	Part D
29	Dabrafenib	Tafinlar	GlaxoSmithKline	5/29/2013	X		TAFINLAR is a **kinase inhibitor** indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. **Limitation of use:** TAFINLAR is not indicated for treatment of patients with wild-type BRAF melanoma.		YES 20130718	oral	Part D
30	Dapsone topical gel	Aczone	Allergan, Inc.	7/7/2005			ACZONE Gel is indicated for the topical treatment of acne vulgaris.		YES 20130320	topical	Part D
31	Decitabine	Dacogen	Eisai Inc	3/11/2010	X		Dacogen is a **nucleoside metabolic inhibitor** indicated for treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate2, and high-risk International Prognostic		YES 20130320	i.v.	Part B
32	Deferiprone	Ferriprox		10/14/2011	X		FERRIPROX (deferiprone) is an **iron chelator** indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate		YES 20130320	oral	Part D
33	Dimethyl fumarate	Tecfidera	Biogen Idec	3/27/2013	X		TECFIDERA is indicated for the treatment of patients with relapsing forms of multiple sclerosis	**X**	YES 20130517	oral	Part D
34	Dolutegravir	Tivicay	GlaxoSmithKline	8/12/2013	X		TIVICAY is a human immunodeficiency virus type 1 (HIV-1) **integrase strand transfer inhibitor** (INSTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and children aged 12 years and older and weighing at least		YES 20130924	oral	Part D
35	Doxylamine Succinate/ Pyridoxine Hydrochloride	Diclegis	Duchesnay	4/8/2013			DICLEGIS is a fixed dose combination drug product of doxylamine succinate, an **antihistamine**, and pyridoxine hydrochloride, a **Vitamin B6 analog**, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to		pending	oral	Part D (pending)

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
36	Efavirenz/ Emtricitabine/ Tenofovir disoproxil fumarate	Atripla	Gilead Sciences	7/12/2006			ATRIPLA, a combination of 2 **nucleoside analog HIV-1 reverse transcriptase inhibitors** and 1 **non-nucleoside HIV-1 reverse transcriptase inhibitor**, is indicated for use alone as a complete regimen or in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.		YES 20130718	oral	Part D
37	Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate	Stribild	Gilead Sciences	8/27/12	X		STRIBILD, a combination of 1 **integrase strand transfer inhibitor**, 1 **pharmacokinetic enhancer,** and 2 **nucleos(t)ide analog HIV-1 reverse transcriptase inhibitors**, is indicated as a complete regimen for the treatment of HIV-1 infection in adults who are antiretroviral treatment-naïve.		YES 20130320	oral	Part D
38	Emtricitabine/ Rilpivirine / Tenofovir disoproxil fumerate	Complera	Gilead Sciences	8/10/2011			COMPLERA (emtricitabine/rilpivirine/tenofovir disoproxil fumarate) is indicated for use as a complete regimen for the treatment of HIV-1 infection in antiretroviral treatment-naive adult patients with HIV-1 RNA less than or equal to 100,000 copies/mL at the		YES 20130517	oral	Part D
39	Enzalutamide	Xtandi	Astellas Pharma	8/31/2012	X		XTANDI is an **androgen receptor inhibitor** indicated for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel		YES 20130320	oral	Part D
40	Eribulin mesylate	Halaven	EISAI INC	11/15/2010	X		HALAVEN is a **microtubule inhibitor** indicated for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or		YES 20130320	i.v.	Part B/ Part D
41	Eslicarbazepine	Aptiom	Sunovion	11/8/2013	X		APTIOM is indicated as adjunctive treatment of partial-onset seizures.		pending	oral	Part D (pending)
42	Ezogabine	Potiga	GlaxoSmithKline	6/10/2011	X		POTIGA is a **potassium channel opener** indicated as adjunctive treatment of partial-onset seizures in patients aged 18 years and older.	**X**	YES 20130320	oral	Part D
43	Fidaxomicin	Dificid	Optimer Pharm	5/27/2011	X		DIFICID is a **macrolide antibacterial drug** indicated in adults (≥18 years of age) for treatment of Clostridium difficile-associated diarrhea		YES 20130320	oral	Part D

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
44	Fluticasone furoate/Vilanterol inhalation powder	Breo Ellipta	GlaxoSmithKline	5/10/2013	X		BREO ELLIPTA is a combination of fluticasone furoate, an **inhaled corticosteroid (ICS)**, and vilanterol, a **long-acting beta$_2$ adrenergic agonist (LABA)**, indicated for long-term, once-daily, maintenance treatment of airflow obstruction and for reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD). Important limitations: Not indicated for relief of acute bronchospasm or for treatment of asthma		pending	inh	Part D (pending)
45	Gabapentin enacarbil	Horizant	GlaxoSmithKline / XenoPort	4/6/2011	X		HORIZANT is indicated for: treatment of moderate to severe primary Restless Legs Syndrome (RLS) in adults, management of postherpetic neuralgia (PHN) in adults.		YES 20130320	oral	Part D
46	Glycerol phenyl-butyrate	Ravicti	Hyperion Therapeutics)	2/1/2013			RAVICTI is indicated for use as a **nitrogen-binding agent** for chronic management of adult and pediatric patients ≥2 years of age with urea cycle disorders (UCDs) that cannot be managed by dietary protein restriction and/or amino acid supplementation alone. RAVICTI must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements).		YES 20130718	oral	Part D
47	Ibrutinib	Imbruvica	Pharmacyclics	11/13/2013	X		IMBRUVICA is a **kinase inhibitor** indicated for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is based on overall response rate. An improvement in survival or disease-related symptoms has not been established	**X**	pending	oral	Part D (pending)
48	Icatibant	Firazyr	Shire	8/25/2011	X		FIRAZYR is a **bradykinin B2 receptor antagonist** indicated for treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older	**X**	YES 20130320	s.q.	Part D
49	Icosapent ethyl	Vascepa	Amarin Pharma	7/26/2012			VASCEPA is an **ethyl ester of eicosapentaenoic acid (EPA)** indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.Limitations of Use: The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. The effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.		YES 20130320	oral	Part D

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
50	Imiglucerase	Cerezyme	Genzyme	5/23/1994	X		Cerezyme (imiglucerase for injection) is indicated for long-term enzyme replacement therapy for pediatric and adult patients with a confirmed diagnosis of Type 1 Gaucher disease		YES 20130517	i.v.	Part B/ Part D
51	Indacaterol inhalation powder	Arcapta Neohaler	Novartis	7/1/2011	X		ARCAPTA NEOHALER is a **long-acting beta2-adrenergic agonist** indicated for: The long term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Important limitations: ARCAPTA NEOHALER is NOT indicated to treat acute deteriorations of chronic obstructive pulmonary disease. ARCAPTA NEOHALER is NOT indicated for asthma.		YES 20130320	i.v.	Part D
52	Ingenol mebutate	Picato	LEO Pharma	1/23/2012	X		Picato gel is an **inducer of cell death** indicated for the topical treatment of actinic keratosis.	**X**	YES 20130320	topical	Part D
53	Ipilimumab	Yervoy	BMS	3/25/2011		X	YERVOY is a **human cytotoxic T-lymphocyte antigen 4 (CTLA-4)-blocking antibody** indicated for the treatment of unresectable or metastatic melanoma	**X**	YES 20130320	i.v.	Part B
54	Ivacaftor	Kalydeco	Vertex	1/31/12	X		KALYDECO is classified as a **cystic fibrosis transmembrane conductance regulator (CFTR) potentiator.** KALYDECO is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the G551D mutation	**X**	YES 20130320	oral	Part D
55	Levoleucovorin	Fusilev	Spectrum Pharmaceuticals	3/7/2008			Fusilev is a **folate analog** indicated for: 1) Rescue after high-dose methotrexate therapy in osteosarcoma. 2) Diminishing the toxicity and counteracting the effects of impaired methotrexate elimination and of inadvertent overdosage of folic acid antagonists 3) Use in combination chemotherapy with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer.Limitations of Use: Fusilev is not approved for pernicious anemia and megaloblastic anemias. Improper use may cause a hematologic remission while neurologic manifestations continue to progress.		YES 20130320	i.v.	Part B

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
56	Levomilnacipran hydrochloride	Fetzima	Forest Labs Inc	7/25/2013			FETZIMA is a **serotonin and norepinephrine reuptake inhibitor (SNRI)** indicated for the treatment of Major Depressive Disorder (MDD) Limitation of Use: FETZIMA is not approved for the management of fibromyalgia. The efficacy and safety of FETZIMA for the management of fibromyalgia have not been established		pending	oral	Part D (pending)
57	Linaclotide	Linzess	Forest Laboratories	8/30/12	X		LINZESS is a **guanylate cyclase-C agonist** indicated in adults for treatment of: Irritable bowel syndrome with constipation (IBS-C) , Chronic idiopathic constipation (CIC)	**X**	YES 20130320	oral	Part D
58	Linagliptin	Tradjenta	Boehringer Ingelheim	5/2/2011	X		TRADJENTA is a **dipeptidyl peptidase-4 (DPP-4) inhibitor** indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus .Important limitations of use: Should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis		YES 20130320	oral	Part D
59	Lomitapide	Juxtapid	Aegerion Pharaceuticals	12/21/12	X		JUXTAPID is a **microsomal triglyceride transfer protein inhibitor** indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH) (1).Limitations of Use:The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH (1). The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined	**X**	YES 20130320	oral	Part D
60	Luliconazole	Luzu	MEDICIS	11/14/2013	X		LUZU (luliconazole) Cream, 1% is an **azole antifungal** indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms Trichophyton rubrum and Epidermophyton floccosum, in patients 18 years of age and older.		pending	topical	Part D (pending)

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
61	Macitentan	Opsumit	Actelion	10/18/2013	X		OPSUMIT is an **endothelin receptor antagonist (ERA)** indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression. Disease progression included: death, initiation of intravenous (IV) or subcutaneous prostanoids, or clinical worsening of PAH (decreased 6-minute walk distance, worsened PAH symptoms and need for additional PAH treatment). OPSUMIT also reduced hospitalization for PAH		pending	oral	Part D (pending)
62	Mecamylamine	Vecamyl	Manchester	3/19/2013			For the management of moderately severe to severe essential hypertension and in uncomplicated cases of malignant hypertension.		YES 20130718	oral	Part D
63	Mechlorethamine hydrochloride	Valchlor	Actelion	8/23/2013			VALCHLOR is an **alkylating drug** indicated for the topical treatment of Stage 1A and 1B mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy.		pending	topical	Part D (pending)
64	Mipomersen sodium	Kynamro	Genzyme	1/29/2013	X		KYNAMRO is an **oligonucleotide inhibitor of apolipoprotein B-100 synthesis** indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)	**X**	YES 20130517	s.q.	Part D
65	Mirabegron	Myrbetriq	Astellas Pharma	6/28/2012	X		Myrbetriq is a **beta-3 adrenergic agonist** indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency	**X**	YES 20130320	oral	Part D
66	Mometasone furoate/ Formoterol fumarate dihydrate	Dulera	Merck Sharpe Dohme	6/22/2010			DULERA is a combination product containing a **corticosteroid** and a **long-acting beta$_2$-adrenergic agonist** indicated for: treatment of asthma in patients 12 years of age and older, and not indicated for the relief of acute bronchospasm.		YES 20130924	inh	Part D
67	Obinutuzumab	Gazyva	Genentech	11/1/2013		X	GAZYVA (obinutuzumab) is a **CD20-directed cytolytic antibody** and is indicated, in combination with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia		pending	i.v.	Part B

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
68	Ofatumumab	Arzerra	GlaxoSmithKline	10/26/2009		X	ARZERRA (ofatumumab) is a **CD20-directed cytolytic monoclonal antibody** indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab. The effectiveness of ARZERRA is based on the demonstration of durable objective responses. No data demonstrate an improvement in disease-related symptoms or increased survival with ARZERRA.		YES 20130718	i.v.	Part B
69	Omacetaxine mepesuccinate	Synribo	Teva/Cephalon	10/26/2012	X		SYNRIBO for Injection is indicated for the treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI). This indication is based upon response rate. There are no trials verifying an improvement in disease-related symptoms or increased survival with	**X**	YES 20130320	s.q.	Part B
70	Omega-3-acid ethyl esters	Lovaza	SmithKline Beecham	11/10/2004	X		LOVAZA (omega-3-acid ethyl esters) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Limitations of Use: The effect of LOVAZA on cardiovascular mortality and morbidity in patients with elevated triglycerides has not been		YES 20130517	oral	Part D
71	Ospemifene	Osphena	Shionogi Pharma	2/26/2013	X		OSPHENA is an **estrogen agonist/antagonist** indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause		pending	oral	Part D (pending)
72	Paroxetine	Brisdelle	Noven Therapeutics	6/28/2013			BRISDELLE is a **selective serotonin reuptake inhibitor (SSRI)** indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause (VMS). Limitation of Use: BRISDELLE is not indicated for the treatment of any psychiatric		YES 20130914	oral	Part D
73	Pasireotide	Signifor	Novartis	12/14/2012	X		SIGNIFOR is a **somatostatin analog** indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative	**X**	YES 20130517	s.q.	Part B/ Part D
74	Perampanel	Fycompa	Eisai	10/22/2012	X		FYCOMPA, a **non-competitive AMPA glutamate receptor antagonist,** is indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older	**X**	pending	oral	Part D (pending)

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
75	Pertuzumab	Perjeta	Genentech	6/8/2012		X	PERJETA is a **HER2/neu receptor antagonist** indicated in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease		YES 20130320	i.v.	Part B
76	Pomalidomide	Pomalyst	Celgene	2/8/2013	X		POMALYST is a **thalidomide analogue** indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.		YES 20130320	oral	Part D
77	Ponatinib	Iclusig	Ariad Pharmaceuticals	12/14/2012	X		Iclusig is a **kinase inhibitor** indicated for the treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy (1). This indication is based upon response rate. There are no trials verifying an improvement in disease-related symptoms or increased survival with		YES 20130320	oral	Part D
78	Pralatrexate	Folotyn	Allos	9/24/2009	X		FOLOTYN is a **folate analog metabolic inhibitor** indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is based on overall response rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated.		YES 20130320	i.v.	Part B
79	Regorafenib	Stivarga	Bayer Healthcare Pharmaceuticals	9/27/2012	X		Stivarga is a **kinase inhibitor** indicated for the treatment of patients with: Metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy. Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.		YES 20130320	oral	Part D

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
80	Rilpivirine	Edurant	Janssen Pharmaceuticals	5/20/2011	X		EDURANT is a **human immunodeficiency virus type 1 (HIV-1) specific, non-nucleoside reverse transcriptase inhibitor (NNRTI)** indicated: In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve adult		YES 20130320	oral	Part D
81	Riociguat	Adempas	Bayer	10/9/2013	X		Adempas is a **soluble guanylate cyclase (sGC) stimulator** indicated for the treatment of adults with: persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class, and Pulmonary Arterial Hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening.	**X**	pending	oral	Part D (pending)
82	Rivaroxaban	Xarelto	Janssen Pharmaceuticals	7/1/2011	X		XARELTO is a **factor Xa inhibitor** indicated: to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation . for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE, for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip		YES 20130320	oral	Part D
83	Roflumilast	Daliresp	FOREST RES INST INC	2/28/2011	X		DALIRESP is indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Limitations of Use: DALIRESP is not a bronchodilator and is not indicated for the relief of acute bronchospasm.	**X**	YES 20130320	oral	Part D
84	Rotigotine	Neupro	UCB	4/6/2012	X		Neupro is a **dopamine agonist** indicated for the treatment of 1) Signs and symptoms of Parkinson's disease, 2) Moderate-to-severe primary Restless Legs Syndrome		YES 20130320	Trans dermal	Part D
85	Ruxolitinib	Jakafi	Incyte	11/16/2011	X		Jakafi is a **kinase inhibitor** indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis	**X**	YES 20130320	oral	Part D
86	Sacrosidase	Sucraid	mulitple	4/9/1998	X		SUCRAID (sacrosidase) oral solution is indicated as oral replacement therapy of the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).		YES 20130517	oral	Part D

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
87	Simeprevir	Olysio	Janssen Pharmaceuticals	11/22/2013	X		OLYSIO is a **hepatitis C virus (HCV) NS3/4A protease inhibitor** indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. OLYSIO efficacy has been established in combination with peginterferon alfa and ribavirin in HCV genotype 1 infected subjects with compensated liver disease (including cirrhosis). OLYSIO must not be used as monotherapy. Screening patients with HCV genotype 1a infection for the presence of virus with the NS3 Q80K polymorphism at baseline is strongly recommended. Alternative therapy should be considered for patients infected with HCV genotype 1a		pending	oral	Part D (pending)
88	Sodium picosulfate, magnesium oxide and citric acid	Prepopik	Ferring B.V.	7/16/2012	X		PREPOPIK is a combination of sodium picosulfate, a **stimulant laxative**, and magnesium oxide and anhydrous citric acid which form magnesium citrate, an **osmotic laxative**, indicated for cleansing of the colon as a preparation for colonoscopy in adults		YES 20130320	oral	Part D
89	Sofosbuvir	Sovaldi	Gilead Sciences	12/06/2013	X		SOVALDI is a **hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor** indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. SOVALDI efficacy has been established in subjects with HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection.	**X**	pending	oral	Part D (pending)
90	Spinosad	Natroba	ParaProl	1/18/2011	X		NATROBA Topical Suspension is a **pediculicide** indicated for the topical treatment of head lice infestations in patients four (4) years of age and older.		YES 20130718	topical	Part D
91	Sucroferric oxyhydroxide	Velphoro	Vifor Fresenius Medical Care Renal Pharma France	11/27/2013			Velphoro is a **phosphate binder** indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis		pending	oral	Part D (pending)
92	Tadalafil	Cialis	Eli Lilly and Company	11/21/2003	X		CIALIS is a **phosphodiesterase 5 (PDE5) inhibitor** indicated for the treatment of: erectile dysfunction (ED), the signs and symptoms of benign prostatic hyperplasia (BPH), ED and the signs and symptoms of BPH (ED/BPH)		YES 20130320	oral	Part D

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
93	Tafluprost	Zioptan	Merck Sharpe Dohme	2/10/2012	X		ZIOPTAN (tafluprost ophthalmic solution) 0.0015% is a **prostaglandin analog** indicated for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.		YES 20130320	ophth	Part D
94	Taliglucerase alfa	Elelyso	Pfizer	5/1/2012	X		ELELYSO(taliglucerase alfa) for injection is a **hydrolytic lysosomal glucocerebroside-specific enzyme** indicated for long-term enzyme replacement therapy (ERT) for patients with a confirmed diagnosis of Type 1 Gaucher disease		YES 20130320	i.v.	Part B/ Part D
95	Teduglutide	Gattex	NPS Pharma Inc	12/21/2012	X		GATTEX (teduglutide [rDNA origin]) for injection is a **glucagon-like peptide-2 (GLP-2) analog** indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support	**X**	YES 20130320	s.q.	Part D
96	Telaprevir	Incivek	Vertex	5/23/2011	X		INCIVEK is a **hepatitis C virus (HCV) NS3/4A protease inhibitor** indicated, in combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 chronic hepatitis C (CHC) in adult patients with compensated liver disease, including cirrhosis, who are treatment-naïve or who have been previously treated with interferon-based treatment, including prior null responders, partial responders, and relapsers. (1) INCIVEK must not be used as monotherapy and must only be used in combination with peginterferon alfa and ribavirin. A high proportion of previous null responders (particularly those with cirrhosis) did not achieve Sustained Virologic Response (SVR) and had telaprevir resistance-associated substitutions emerge on treatment with INCIVEK.		YES 20130320	oral	Part D
97	Temsirolimus	Torisel	Wyeth Pharmaceuticals	5/30/2007	X		TORISEL is a **kinase inhibitor** indicated for the treatment of advanced renal cell carcinoma.		YES 20130517	i.v.	Part B/ Part D
98	Teriflunomide	Aubagio	Genzyme	09/12/2012	X		AUBAGIO is a **pyrimidine synthesis inhibitor** indicated for the treatment of patients with relapsing forms of multiple sclerosis	**X**	YES 20130320	oral	Part D

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
99	Ticagrelor	Brilinta	AstraZeneca	7/20/2011	X		BRILINTA is a **P2Y12 platelet inhibitor** indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction). BRILINTA has been shown to reduce the rate of a combined endpoint of cardiovascular death, myocardial infarction, or stroke compared to clopidogrel. The difference between treatments was driven by CV death and MI with no difference in stroke. In patients treated with PCI, it also reduces the rate of stent thrombosis. (1) BRILINTA has been studied in ACS in combination with aspirin. Maintenance doses of aspirin above 100 mg decreased the effectiveness of BRILINTA. Avoid maintenance doses of aspirin above 100 mg daily		YES 20130320	oral	Part D
100	Tinidazole	Tinidazole	mulitple	4/30/2012			Tinidazole Tablets is a **nitroimidazole antimicrobial** indicated for: Trichomoniasis, Giardiasis: in patients age 3 and older, Amebiasis: in patients age 3 and older, Bacterial Vaginosis: in non- pregnant, adult		YES 20130320	oral	Part D
101	Tocilizumab	Actemra	Genentech	10/21/2013		X	ACTEMRA (tocilizumab) is an **interleukin-6 (IL-6) receptor antagonist** indicated for treatment of: 1) Rheumatoid Arthritis (RA): Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).2) Polyarticular Juvenile Idiopathic Arthritis (PJIA): Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis. 3) Systemic Juvenile Idiopathic Arthritis (SJIA): Patients 2 years of age and older with active systemic juvenile idiopathic arthritis		YES 20130924	i.v. s.q.	Part B/ Part D
102	Tofacitinib	Xeljanz	Pfizer	11/06/2012	X		XELJANZ, an **inhibitor of Janus kinases (JAKs),** is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). XELJANZ should not be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.		YES 20130320	oral	Part D

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
103	Trametinib	Mekinist	GlaxoSmithKline	5/29/2013	X		MANUFACTURER REQUESTED USP STAFF EVAL.MEKINIST is a **kinase inhibitor** indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. **Limitation of use:** MEKINIST is not indicated for the treatment of patients who have received prior BRAF-inhibitor	**X**	YES 20130718	oral	Part D
104	Trastuzumab	Herceptin	Genentech	9/25/1998		X	Herceptin is a **HER2/neu receptor antagonist** indicated for: 1) the treatment of HER2 overexpressing breast cancer, 2) the treatment of HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma		YES 20130517	i.v.	Part B
105	Vandetanib	Caprelsa	AstraZeneca	4/6/2013	X		CAPRELSA is a **kinase inhibitor** indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. (1) Use of CAPRELSA in patients with indolent, asymptomatic or slowly progressing disease should be carefully considered because of the treatment related risks of		YES 20130320	oral	Part D
106	Velaglucerase alfa	Vpriv	Shire US	12/26/2010	X		VPRIV (velaglucerase alfa for injection) is a **hydrolytic lysosomal glucocerebroside-specific enzyme** indicated for long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease		YES 20130517	i.v.	Part B/ Part D
107	Vemurafenib	Zelboraf	Genentech	8/17/2011	X		ZELBORAF is a **kinase inhibitor** indicated for the treatment of patients with unresectable or metastatic melanoma with BRAFV600E mutation as detected by an FDA-approved test. Limitation of Use: ZELBORAF is not recommended for use in patients with wild-type BRAF melanoma.	**X**	YES 20130320	oral	Part D
108	Vilazodone hydrochloride	Viibryd	FOREST LABS INC	1/21/2011	X		VIIBRYD is indicated for the treatment of major depressive disorder (MDD). The efficacy of VIIBRYD was established in two 8-week, placebo-controlled trials in adult patients with MDD		YES 20130320	oral	Part D
109	Vismodegib	Erivedge	Genentech	1/30/2012	X		ERIVEDGE (vismodegib) capsule is a **hedgehog pathway inhibitor** indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.	**X**	YES 20130320	oral	Part D

	Active Ingredient	Brand Name	Manufacturer	FDA Approval Date	NME	BLA	FDA Indication	FDA First in class	CMS FRF Inclusion (YrMoDy)*	ROA	Eligibility
110	Vorinostat	Zolinza	Merck	10/6/2006	X		ZOLINZA is a **histone deacetylase (HDAC) inhibitor** indicated for the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies.		YES 20130718	oral	Part D
111	Vortioxetine	Brintellex	Takeda	9/30/2013	X		BRINTELLIX is indicated for the treatment of major depressive disorder (MDD)	**TBD**	pending	oral	Part D (pending)
112	Ziv-aflibercept	Zaltrap	Sanofi-aventis	08/03/2012		X	ZALTRAP, in combination with 5-fluorouracil, leucovorin, irinotecan-(FOLFIRI), is indicated for patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.		YES 20130320	i.v.	Part B

Appendix VI: Stakeholder 1:1 Consultations

Stakeholder	Topic	USP Category/Class	Summary of Consultation	TIFS EC Decision/Rationale
Alcon	SIMBRINZA	Ophthalmic Agents	The information presented in this consultation provides supplemental material for EC consideration. The consultation explores the application of the Guiding Principles to combination ophthalmic preparations, with respect to patient outcomes (efficacy and safety).	According to Guiding Principles, combination products are not included in the USP MMG unless there is a scientifically valid and clinically meaningful attendant patient care need. Insufficient evidence was provided by stakeholder, and absent in the literature to support the addition of this product to the model guidelines.
AMCP	Managed Care Pharmacy Feedback	GENERAL	The information presented in this consultation provides supplemental information. The comments are consistent with TIFS EC Guiding Principles, and provide suggestions for improving the usability of the Model Guidelines.	EC acknowledges stakeholder comments, and will utilize the RxCUI suggestion in the final USP MMG v6 alignment with the CMS CY14 FRF.
Amgen	Immunological Agents	Immunological Agents	The information presented in this consultation is consistent with the current placement of TNF-blockers in the USP Model Guidelines v5.0. Amgen is requesting elevation of the Pharmacotherapeutic Group to a USP Class.	There is insufficient evidence to create expanded USP classes for the Medicare Part D uses of the USP MMG.
Amgen	Biosimilars	GENERAL	This consultation was informational only, and does not inform any decision making relevant to TIFS EC current evaluation of the USP Model Guidelines. The biosimilar topic may be of greater interest to the EC in early 2014 when they begin to work on other therapeutic information topics.	n/a

Stakeholder	Topic	USP Category/Class	Summary of Consultation	TIFS EC Decision/Rationale
Amgen	Denosumab (PROLIA, XGEVA)	Metabolic Bone Disease	The data presented in this consultation is consistent with the current placement of denosumab in the USP Model Guidelines v5.0 under ***USP Category: Metabolic Bone Disease Agents***, ***USP Class: none*****,** ***Pharmacotherapeutic Group: RANK Ligand Inhibitor*****.** Denosumab was FDA approved on 6/1/2010 as both PROLIA and XGEVA.	There is no additional information on new therapeutic uses which would warrant Expert Committee re-evaluation of position of denosumab in the Model Guidelines.
Amgen	Dermatological Agents- TNF Blockers	Dermatological Agents	The data presented in this consultation is consistent with the drug information provided to the TIFS EC, and represents an alternative viewpoint to the USP MMG v6.0 Draft #2. In USP MMGv5.0, there are no USP Classes under the ***USP Category: Dermatological Agents.*** .	There is insufficient evidence to create expanded USP classes for the Medicare Part D uses of the USP MMG. Placement of TNF-blockers in this USP Category would be a second placement in the USP Model Guidelines, against Guiding Principles.
ASAM	Anti-addiction drugs	Anti-addiction/ Substance Abuse Treatment Agents	The data presented in this consultation provides supplemental material that may be useful for EC consideration. ASAM is proposing that there should be four (4) USP Classes to accommodate the difference in use and Medicare Part D patient access to the treatments for opioid dependence (methadone, buprenorphine, naltrexone and naloxone). In 9/2011, OAG issued a report that identified the excessive overutilization of prescription opioids in the Medicare Part D beneficiaries; sub sequentially, CMS instituted quality programs regarding appropriate opioid prescribing. Due to federal regulations, there are access barriers to 2 of the 3 treatments for opioid dependence (i.e., methadone, buprenorphine). Oral and extended-release injectable forms of naltrexone have different FDA indications regarding use in opioid treatment. There are also different safety profiles between the dosage forms. Only oral naltrexone has a Black Box Warning for Hepatotoxicity. The FDA removed hepatotoxicity warnings on extended-release injectable naltrexone 7/2013	EC restructured the Opioid Dependence Treatments and Opioid Reversal Agents. Methadone is excluded by CMS regulations for the treatment of opioid dependence due to the federal regulations regarding dispensing facilities.

Stakeholder	Topic	USP Category/Class	Summary of Consultation	TIFS EC Decision/Rationale
Astellas	Mirabegron (MYRBETRIQ)	Genitourinary Agents	The data presented in this consultation is consistent with the drug information provided to the TIFS EC, and represents an alternative viewpoint to the USP MMG v6.0 Draft #2, which differentiates at the level of two new Pharmacotherapeutic Groups, Beta3- Adrenergic Agonists and Cholinergic Muscatine Antagonists. Stakeholder is recommending that similar designations be made at the USP Class level.	Prior to consultation, USP independently placed mirabegron. Information in this stakeholder consultation supported that placement, and did not provide sufficient information to create a single-drug class containing only mirabegron. Mirabegron had not yet been evaluated or included in treatment guidelines for OAB
Astellas	Enzalutamide (XTANDI)	Antineoplastics	The data presented in this consultation is consistent with the drug information provided to the TIFS EC, and represents an alternative viewpoint to the USP MMG v6.0 Draft #2. Stakeholder suggests that it may not be appropriate to classify all of the antiandrogens in the same USP Class. While enzalutamide pharmacology is similar to the other antiandrogens (flutamide/bicalutamide /nilutamide), enzalutamide may be considered a 'second generation' antiandrogen due to its pure antagonist effect and intracellular MOA. Currently, there are other 'second generation' agents being developed. There have been no head-head studies comparing the antiandrogens NCCN Guidelines consider all antiandrogens in the same group,	EC restructured ***Antiandrogens*** and placed under ***Antineoplastics*** in the final USP MMG v6.0, consistent with data presented during stakeholder meeting.
Boehringer-Ingelheim	Linagliptin (TRADJENTA)	Blood Glucose Regulators	The information presented in this consultation is consistent with the drug information provided to the TIFS EC, and supports current USP MMG v6.0 Draft #2.	Prior to consultation, USP independently reviewed Linagliptin and placed in the ***Blood Glucose Regulators, Antidiabetic Agents .***

Stakeholder	Topic	USP Category/Class	Summary of Consultation	TIFS EC Decision/Rationale
Boehringer-Ingelheim	COMBIVENT RESPIMAT	***Respiratory Tract Agents***	The data presented in this consultation represents an alternative viewpoint to the USP MMG v6.0 Draft #2. This product has neither a new indication nor new therapeutic use; it is a reformulated inhaler. In USP MMGv5.0, the combination of ipratropium bromide and albuterol is not specifically listed, as each component has placement on the MG.	According to Guiding Principles, combination products are not included in the USP MMG unless there is a scientifically valid and clinically meaningful attendant patient care need. Insufficient evidence was provided by stakeholder, and absent in the literature to support the addition of this product to the model guidelines.
Boehringer-Ingelheim	afatinib (GILOTRIF)	***Antineoplastics***	The information provided in this consultation provides new material that may be useful for EC consideration. Afatinib was FDA approved on July 12, 2013, The consultation suggests that afatinib be added to USP Category, Antineoplastics; USP Class: Molecular Targeted Inhibitors, USP Pharmacotherapeutics Group: Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitors, in same grouping as erlotinib.	Prior to consultation, USP independently reviewed afatinib and placed in ***Antineoplastics, Molecular Targeted Inhibitors.*** Placement was consistent with data presented by stakeholder.
Forest	Cetaroline (TEFLARO)	***Antibacterials***	The data presented in this consultation is consistent with the drug information provided to the TIFS EC, and represents an alternative viewpoint to the USP MMG v6.0 Draft #2. The stakeholder suggests an appropriate classification may be a new USP Class: “Beta-Lactams, Cephalosporins with MRSA Activity”. The consultation suggests that providers may be confused by a designation of “Cephalosporin Antibacterials, 5th Generation” Ceftaroline fosamil is only FDA indicated for MRSA in ABSSSI, not in CAPB. Ceftaroline fosamil is currently under investigation for adults with CABP at risk for MRSA.	USP MMG Antibiotics are are defined by pharmacology, not according to spectrum of activity. Given the shifting patterns of resistance, EC maintains the placement of cetaroline, which will support local/regional P&T Committees flexibility in defining MRSA agents.

Stakeholder	Topic	USP Category/Class	Summary of Consultation	TIFS EC Decision/Rationale
Forest	Linaclotide (LINZESS)	***Gastrointestinal Agents***	The data presented in this consultation is consistent with the drug information provided to the TIFS EC, and represents an alternative viewpoint to the USP MMG v6.0 Draft #2. The consultation suggests removing the USP Class: Irritable Bowel Syndrome Agents, and creating three new USP Classes: "Irritable Bowel Syndrome with Constipation Agents", Irritable Bowel Syndrome with Diarrhea Agents", and "Chronic Idiopathic Constipation Agents".	Prior to consultation, USP independently reviewed linaclotide. Insufficient evidence to support creation of two 2-drug USP Classes, and one 1-drug USP Class.
Forest	Roflumilast (DALIRESP)	***Respiratory Tract Agents***	The data presented in this consultation is consistent with the independent drug information provided to the TIFS EC, and supports current USP MMG v6.0 Draft #2.	Expert Committee placed roflumilast in the renamed USP Class , ***Phosphodiesterase Inhibitors, Airways Disease***
Forest	Aclidinium Br (TUDORZA)	***Respiratory Tract Agents***	The data presented in this consultation is consistent with the drug information provided to the TIFS EC, and represents an alternative viewpoint to the USP MMG v6.0 Draft #2. Stakeholder suggests that LAMA and SAMA agents should be separated on the USP MMG to parallel the treatment guideline classification of these agents.	There is insufficient evidence to create expanded USP classes for the Medicare Part D uses of the USP MMG.
Forest	Levomilnacipran (FETZIMA)	***Antidepressants***	This consultation was a clinical development overview of levomilnacipran prior to FDA approval.	Levomilnacipran was approved by the FDA and was independently reviewed by the EC; levomilnacipran was placed on the USP MMG consistent with the data presented in this stakeholder meeting.
Forest	Vilazodone (VIIBRYD)	***Antidepressants***	The data presented in this consultation is consistent with the drug information provided to the TIFS EC, and supports current USP MMG v6.0 Draft #2.	Vilazodone was independently placed on the USP MMG consistent with the data presented by this stakeholder.
Forest	Cariprazine (NDA)	***Antipsychotic Agents, Bipolar Agents***	The consultation was a clinical development overview of cariprazine prior to FDA approval.	Cariprazine was not approved by the FDA during this revision cycle.

Stakeholder	Topic	USP Category/Class	Summary of Consultation	TIFS EC Decision/Rationale
Gilead	COMPLERA-STRIBILD	***Antivirals***	The information presented in this consultation was consistent with the independent drug information review conducted by the TIFS EC. Supplemental material was provided, including market insight into other agents entering the US market in 2013 (e.g., dolutegravir), which provides support for three drugs in the US market as "Integrase Inhibitors".	Prior to consultation, USP independently placed Complera in ***Antivirals, Anti-HIV Agents, NNRTI*** and Stribild, dolutegravir, and raltegravir in new USP class ***Anti-HIV Agents, INSTIs***. Information in this consultation provided information supporting the final TIFS recommendations.
Gilead	Sofosbuvir (NDA)	***Antivirals***	The information presented in this consultation provided a clinical development overview of sofosbuvir prior to FDA approval.	Upon FDA approval of sofosbuvir, USP reviewed clinical data and approved PI and placed sofosbuvir in ***Antivirals, Anti-hepatitis C (HCV) Agents***
GSK	Anti-HIV Classes: Dolutegravir (GSK), Maraviroc	***Antivirals***	The information presented in this consultation provided a clinical development overview of dolutegravir prior to FDA approval.	Prior to consultation, USP independently placed dolutegravir, Stribild and raltegravir in new USP class ***Anti-HIV Agents, INSTIs.*** . At the current time, there is insuffient information to create a single-drug class for maraviroc.
GSK	Albiglutide (NDA)	***Blood Glucose Regulators***	The information presented in this consultation provided a clinical development overview of albiglutide prior to FDA approval.	Albiglutide was not approved by the FDA during this revision cycle.
GSK	BREO ELLIPTA	***Respiratory Tract Agents***	The data presented in this consultation provides supplemental material that may be useful for EC consideration of placement of newly approved BreoEllipta, and another product (Umeclidinium Bromide and Vilanterol) with a December 2013 PDUFA date.	BreoEllipta was placed by the EC in ***Respiratory Tract, Others***. Umeclidinium Bromide and Vilanterol was not FDA approved during this revision cycle.

Stakeholder	Topic	USP Category/Class	Summary of Consultation	TIFS EC Decision/Rationale
GSK	Ofatumumab, Trametinib, Dabrafenib	***Antineoplastics***	The data presented in this consultation is consistent with the drug information provided to the TIFS EC	These Part B/Part D drugs were placed by the EC on the USP MMGv6.0
Novo Nordisk	Blood Glucose Regulators	***Blood Glucose Regulators***	The information presented in this consultation is consistent with the current USP Model Guidelines v5.0, and suggests that the Pharmacotherapeutic Groups should be displayed on the USP MMG v6.0 to improve stakeholder understanding and use of the Model Guidelines.	There is insufficient evidence to create expanded USP classes for the Medicare Part D uses of the USP MMG.
Novo Nordisk	Somatropin	***Hormonal Agents***	The data presented in this consultation represents an alternative viewpoint to the USP MMG v5.0. The current ***USP Category: Hormonal Agents, Stimulant/ Replacement/ Modifying (Pituitary)*** has no USP Classes, and four (4) USP ***Pharmacotherapeutic Groups:*** *Gonadotropins, Growth Hormone Analogs* (which includes Somatropin, Recombinant), *Insulin-like Growth Factor Analogs*, and *Vasopressin Analogs*. This consultation is suggesting that it would be beneficial to create to different USP Classes based on therapeutics, "*Pituitary axis growth replacement*" and "*Pituitary, other*".	There is insufficient evidence to create expanded USP classes for the Medicare Part D uses of the USP MMG.
Optimer	Fidaxomicin (DIFFICID)	***Antibacterials***	The information presented in this consultation provides supplemental material, and represents an alternative viewpoint to the USP MMG v6.0 Draft #2. This consultation outlines Medicare Part D beneficiary access issues and CMS quality programs for C-difficile-associated diarrhea (CDAD) in adults >18 years, which may be impacted by lack of continuity of care (inpatient-to-outpatient) as Medicare beneficiaries transition	At the current time, there is insufficient evidence to create a single-drug class for fidamoxicin.
Pfizer	Immunological Agents	***Immunological Agents***	The information presented in this consultation is consistent with the current USP Model Guidelines v5.0, and suggests that the Pharmacotherapeutic Groups should be displayed on the USP MMG v6.0 to improve stakeholder understanding and use of the Model Guidelines.	There is insufficient evidence to create expanded USP classes for the Medicare Part D uses of the USP MMG.

Stakeholder	Topic	USP Category/Class	Summary of Consultation	TIFS EC Decision/Rationale
Pfizer	Oral Anticoagulants	***Blood Products/ Modifiers/ Volume Expanders***	The data presented in this consultation is consistent with the drug information provided to the TIFS EC, and represents an alternative viewpoint to the USP MMG v6.0 Draft #2 . Stakeholder suggests the reclassification of the ***USP Class: Anticoagulants*** Pharmacotherapeutic Groups to accommodate dosage route (oral vs injectable) and to elevate to USP Class level.	There is insufficient evidence to create expanded USP classes for the Medicare Part D uses of the USP MMG. There is insufficient evidence to create USP Classes with single drugs.
SAMHSA	Opioid Dependence Treatments	***Anti-addiction/ Substance Abuse Treatment Agents***	This consultation is very similar to the comments provided by ASAM. Some considerations raised by the SAMSHA include: Re-titling the USP Class: Opioid Antagonists to reflect the concept of Opioid Dependence Treatment as listed in DSM-5 ; Adding methadone to the re-titled USP Class for Opioid SUD Treatments"; Creating Pharmacotherapeutic Groups or USP Classes to distinguish between maintenance treatments: antagonists (naltrexone), agonists (methadone) and partial agonists (buprenorphine, buprenorphine/ naloxone); Identifying naloxone is an antidote for overdose, not a maintenance treatment; Considering an exception to the MG combination product Guiding Principle for the buprenorphine/naloxone combination.	EC restructured the ***Opioid Dependence Treatments*** and ***Opioid Reversal Agents.*** Methadone is excluded by CMS regulations for the treatment of opioid dependence due to the federal regulations regarding dispensing facilities.
Sanofi	Lixisenatide (NDA)	***Blood Glucose Regulators***	The information presented in this consultation provided a clinical development overview of lixensinatide prior to FDA approval.	Lixisenatide was not approved by the FDA during this revision cycle.
Takeda/ Lundbeck	Vortioxetine (NDA)	***Antidepressants***	This consultation was a clinical development overview of vortioxetine prior to FDA approval.	Vortioxetine was approved by the FDA, and placed by the Expert Committee.
Teva	Omacetaxine (SYNRIBO)	***Antineoplastics***	The data presented in this consultation is consistent with the drug information provided to the TIFS EC, and represents an alternative viewpoint to the USP MMG v6.0 Draft #2. This consultation outlines a request to review the ***USP Category: Antineoplastics*** to consider a new USP Class.	Omacetaxine is a Part B drug, and is outside of the scope of USP to place on the USP MMG. Part B eligibility confirmed from CMS (11/2013).

Stakeholder	Topic	USP Category/Class	Summary of Consultation	TIFS EC Decision/Rationale
Vanda	Tasimelteon (NDA)	***Central Nervous System Agents***	This consultation was a clinical development overview of tasimelteon prior to FDA approval.	Tasimelteon was not approved by the FDA during this revision cycle.
Vertex	Ivacaftor (KALYDECO)	***Respiratory Tract Agents***	The data presented in this consultation is consistent with the drug information provided to the TIFS EC, and supports current USP MMG v6.0 Draft #2.	EC placed ivacaftor in new ***Cystic Fibrosis*** USP Class

Appendix VII: Open Microphone Web Meetings

USP Medicare Model Guidelines v6.0
Open Microphone Web Meeting #1
Beneficiaries / Patient Advocacy Groups
Monday, October 21, 2013
11:00 a.m. to 12:20 p.m. EDT
Teleconference

Chair: N. Jo Braden
Scientific Liaison: Jami Earnest
Expert Committee Manager: Ken Freebern
Executive Secretariat Liaison: Scott Kuzner

Notes

Goals and Anticipated Outcomes

- To describe USP and the Expert Committee's role in developing and updating the USP Medicare Model Guidelines (USP MMG)
- To describe the major revisions proposed for USP MMG v6.0
- To solicit specific feedback from interested stakeholders on the structural content and organization of the USP MMG v6.0

Attendees

Expert Committee/ Expert Panel Members
Babette Edgar
Lee Rucker
Marialice Bennett
Russell Teagarden

CMS Liaison
Marie Manteuffel

Public Participants
See Table #1 at the end of the notes

USP Staff
Angela Long, Shawn Becker, Jami Earnest, Ken Freebern, Scott Kuzner

1. Introductions
Dr. Jami Earnest welcomed the group at 11:00 a.m. and described the process for the Open Microphone meeting. USP staff and Expert Committee members introduced themselves over the teleconference. Dr. Earnest explained that in order to ask questions or make comments

during the meeting, participants must be connected to both the WebEx and audio portions. Questions will be collected using the WebEx Q&A process and will be addressed in order.

2. Background on USP Medicare Model Guidelines

Ms. Angela Long reviewed a presentation outlining the background of the U.S. Pharmacopeial Convention, the Council of Experts, the role of USP in creating public standards, and the Medicare Modernization Act of 2003.

3. USP Medicare Model Guidelines v6.0

Dr. Earnest outlined the Guiding Principles for version 6.0 of the USP MMG. The USP MMG are composed of two organizational levels, USP Categories and USP Classes, which characterize the statutory requirement for Medicare Part D plan benefit design to include drugs from each category and class. The USP MMG includes a list of associated drug examples that aligns with the Part D drugs reflected on the Center for Medicare and Medicaid Services (CMS) Formulary Reference File.

Nine new USP Classes will be in version 6.0 of the USP MMG. Two of the USP Classes are nomenclature changes to reflect the therapeutics of the USP Classes. Six new USP Classes are created to accommodate new FDA approved drugs. The Glucocorticoids / Mineralocorticoids USP Class will be removed to broaden the Hormonal agents, Stimulant / Replacement / Modifying (Adrenal) USP Category to include Corticotropin. Nomenclature changes are occurring for the Respiratory Tract Agents USP Category and for five USP Classes.

4. Next Steps

Dr. Earnest explained the public comment period ends on October 31, 2013, and the timeline for the final deliverables to CMS.

5. Open Microphone Q&A Session

Dr. Salvatore Giorgianni Jr. offered a comment on behalf of Men's Health Network, a patient advocacy organization, regarding the ***Irritable Bowel Syndrome (IBS) Agents*** USP Class. The Men's Health Network believes this USP Class should be subdivided to permit new drugs specific to "IBS–Constipation", "IBS-Diarrhea", and "IBS-Chronic Idiopathic Constipation". Dr. Giorgianni further described the USP MMG are not reflective of the standard of care, which distinguishes between these three disease states. He expressed concern that the proposed structure might impede patient access. Dr. Giorgianni highlighted the gender issues related to this therapeutic area, and suggested there should be male gender considerations.

Paul Schroeder of the American Foundation for the Blind requested USP consider adding a "Circadian Rhythm Disorder" Class to accommodate a new drug that is anticipated to be FDA approved soon (tasimelteon). Mr. Schroeder explained that Non-24 is not a sleep-disorder, and tasimelteon should not be considered a sleep disorder treatment. Mr. Schroeder also described the difficulty of the CMS appeals process for patients who are blind, and suggested that proper placement of tasimelteon on the USP MMG might avoid this unnecessary burden on patients. Mr. Schroeder acknowledged the role of the USP in creating categories and classes for approved medications, and requested an exception for consideration of tasimelteon which is expected to be approved in January 2014.

Carl Schmid of The AIDS Institute commented positively about the USP proposed new class for ***Antivirals, INSTIs*** and ***Antivirals, Anti-HCV Agents***. Ms. Schmid asked about a combination drug not listed in the USP MMG (Atripla) which has three components that are separately included in the USP MMG. Ms. Schmid commented that there is an inconsistency of how

combination products are listed in the ***Antivirals, Anti-HIV*** classes, and requested that Atripla be added to the example drug list.

William Norton of the International Foundation for Functional Gastrointestinal Disorders requested USP to consider adding a "Chronic Idiopathic Constipation" as a new USP Class within the ***Gastrointestinal Agents*** USP Category. He further stated that ***Irritable Bowel Syndrome Agents*** should have two classes, "IBS, Constipation" and "IBS, Diarrhea". He did not think it would be appropriate to list "Chronic Idiopathic Constipation" under ***Irritable Bowel Syndrome Agents***, since it was a different disease.

Andrew Sperling of the National Alliance on Mental Illness acknowledged USP adding the ***Benzodiazepines*** USP Class in the ***Anxiolytics*** USP Category. In addition, NAMI is concerned that many drugs with different mechanisms of actions are in the ***Serotonin and/or Norepinephrine Modulators*** USP Class due to the nomenclature change, and requested USP to reevaluate the overall classification in the ***Antidepressants*** Category. Mr. Sperling highlighted the recent efforts of ACNP to separate antidepressants based upon pharmacology. He also stated that vilazodone was not FDA approved as an SSRI, and suggested alternative placement in the USP MMG.

6. Adjourn

The meeting adjourned at 12:20 p.m.

Table 1: Public Participants (10/21/2013)

#	Name	Company
1	Adrianna Simonelli	Pharmaceutical Care Management Association
2	Allen Doederlein	Depression and Bipolar Support Alliance
3	Amanda Seeff-Charny	Forest Labs
4	Amy Killelea	NASTAD.org
5	Andrew Sperling	National Alliance on Mental Illness
6	Beatriz Duque Long	EFA.org
7	Carl Schmid	The AIDS Institute
8	Deborah Walter	Takeda
9	Diane Dorman	National Organization for Rare Disorders
10	Drew Saelens	Applied Policy
11	Elisabeth Daniel	Avalere Health LLC
12	James Russell	GlaxoSmithKline
13	Jamie Sullivan	COPD Foundation
14	Jane Horvath	Merck
15	John Carlsen	Covance Market Access Services Inc.
16	Kim Calder	NMSS.org
17	Kim Ryan	Fight Colorectal Cancer
18	Kristi Guillory	Cancer.org
19	Lynda Bryant-Comstock	GlaxoSmithKline
20	Mary Jo Carden	Academy of Managed Care Pharmacy
21	Meghan Burris	The Herald Group

#	Name	Company
22	Melanie Brunson	Executive Director
23	Pam Traxel	American Cancer Society (ACS CAN)
24	Paul Schroeder	American Foundation for the Blind
25	Rob Haralson	The Herald Group
26	Ronald Johnson	AIDS United
27	Ryan Clary	National Viral Hepatitis Roundtable
28	Salvatore Giorgianni	Men's Health Network
29	William Norton	International Foundation for Functional GI Disorders

USP Medicare Model Guidelines v6.0
Open Microphone Web Meeting #2
Health Plans/PBMs
Tuesday, October 22, 2013
10:00 a.m. to 10:55 a.m. EDT
Teleconference

Chair: N. Jo Braden
Scientific Liaison: Jami Earnest
Expert Committee Manager: Ken Freebern

Notes

Goals and Anticipated Outcomes

- To describe USP and the Expert Committee's role in developing and updating the USP Medicare Model Guidelines (USP MMG)
- To describe the major revisions proposed for USP MMG v6.0
- To solicit specific feedback from interested stakeholders on the structural content and organization of the USP MMG v6.0

Attendees

Expert Committee/Expert Panel Members

1. Bernie Good
2. Russell Teagarden

CMS Liaisons

Marie Manteuffel, Teisha Robertson

Public Participants

See Table #1 at the end of the notes

USP Staff

Angela Long, Shawn Becker, Jami Earnest, Ken Freebern

2. Introductions

Dr. Jami Earnest welcomed the group at 10:00 a.m. and described the process for the Open Microphone meeting. USP staff and Expert Committee members introduced themselves over the teleconference. Dr. Earnest explained that in order to ask questions or make comments during the meeting, participants must be connected to both the WebEx and audio portions. Questions will be collected using the WebEx Q&A process and will be addressed in order.

2. Background on USP Medicare Model Guidelines

Ms. Angela Long reviewed a presentation outlining the background of the U.S. Pharmacopeial Convention, the Council of Experts, the role of USP in creating public standards, and the Medicare Modernization Act of 2003.

3. USP Medicare Model Guidelines v6.0

Dr. Earnest outlined the Guiding Principles for version 6.0 of the USP MMG. The USP MMG are composed of two organizational levels, USP Categories and USP Classes, which characterize the statutory requirement for Medicare Part D plan benefit design to include drugs from each category and class. The USP MMG includes a list of associated drug examples that aligns with the Part D drugs reflected on the Center for Medicare and Medicaid Services (CMS) Formulary Reference File.

Nine new USP Classes will be in version 6.0 of the USP MMG. Two of the USP Classes are nomenclature changes to reflect the therapeutics of the USP Classes. Six new USP Classes are created to accommodate new FDA approved drugs. The Glucocorticoids / Mineralocorticoids USP Class will be removed to broaden the Hormonal agents, Stimulant / Replacement / Modifying (Adrenal) USP Category to include Corticotropin. Nomenclature changes are occurring for the Respiratory Tract Agents USP Category and for five USP Classes.

4. Next Steps

Dr. Earnest explained the public comment period ends on October 31, 2013, and the timeline for the final deliverable to CMS.

5. Open Microphone Q&A Session

A commenter stated that there are many women of child-bearing ages that receive benefit through Medicare. The commenter inquired why there was not a specific therapeutic category for contraceptives in the USP MMG. The commenter urged USP to consider developing such a category, and to include combination products. The commenter suggested this would be a useful tool for the Part D plans. Dr. Earnest clarified that the USP MMG does include the components of contraceptives within the respective hormonal categories, and confirmed that the combination products were aligned on the CMS FRF but did not appear on the sample list.

There were no other comments.

6. Adjourn

The USP appreciates the participants' interest and encouraged them to provide written commentary.

The meeting adjourned at 10:55 a.m.

Table 1: Public Participants (10/22/2013)

#	Name	Company
1	Amanda Seeff-Charny	Forest Labs
2	Annemarie Wouters	Manatt Health Solutions
3	Brenna Jenny	Sidley
4	Bruce Kreter	Gilead Sciences
5	Chuck Cordell	Argus Health Systems
6	Drew Saelens	Applied Policy
7	Elisabeth Daniel	Avalere Health
8	James Russell	GlaxoSmithKline
9	Jane Horvath	Merck

#	Name	Company
10	Jenny Williams	Aetna
11	Jim Hopsicker	MVP Healthcare
12	John Carlsen	Covance
13	Julie Kendle	Aetna
14	Karina Buckner	Advance PCS
15	Kent McKinney	Allergan
16	Kristin Bass	PCMA
17	Lauren Hoffman	Express Scripts
18	Lynda Bryant-Comstock	GlaxoSmithKline
19	Mark Gruenhaupt	Argus Health Systems
20	Mary Jo Carden	AMCP
21	Mary Kay Gilbert	RGA Reinsurance
22	Meghan Burris	The Herald Group
23	Michele Thatcher	Aetna
24	Narda Ipakchi	Manatt Health Solutions
25	Ravi Upadhyay	Genentech
26	Rob Haralson	The Herald Group
27	Stephanie Hales	Sidley
28	Wendy Colin	MVP Healthcare
29	Wendy Krasner	PCMA

USP Medicare Model Guidelines v6.0
Open Microphone Web Meeting #3
Pharmaceutical Manufacturers
Thursday, October 24, 2013
2:00 p.m. to 3:45 p.m. EDT
Teleconference

Chair: N. Jo Braden
Scientific Liaison: Jami Earnest
Expert Committee Manager: Ken Freebern

Notes

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Goals and Anticipated Outcomes

- To describe USP and the Expert Committee's role in developing and updating the USP Medicare Model Guidelines (USP MMG)
- To describe the major revisions proposed for USP MMG v6.0
- To solicit specific feedback from interested stakeholders on the structural content and organization of the USP MMG v6.0

Attendees

Expert Committee/Expert Panel Members

1. Marcus Reidenberg
2. Raymond Hohl
3. Robert Meyer
4. Robert Talbert
5. Seth Powsner

CMS Liaisons
Marie Manteuffel, Teisha Robertson

Public Participants
See Table #1 at the end of the notes

USP Staff
Shawn Becker, Jami Earnest, Ken Freebern

1. Introductions

Dr. Jami Earnest welcomed the group at 2:00 p.m. and described the process for the Open Microphone meeting. USP staff and Expert Committee members introduced themselves over the teleconference. Dr. Earnest explained that in order to ask questions or make comments during the meeting, participants must be connected to both the WebEx and audio portions. Questions will be collected using the WebEx Q&A process and will be addressed in order.

2. Background on USP Medicare Model Guidelines

Dr. Earnest presented some background information about the U.S. Pharmacopeial Convention, the Council of Experts, the role of USP in creating public standards, and the Medicare Modernization Act of 2003.

3. USP Medicare Model Guidelines v6.0

Dr. Earnest outlined the Guiding Principles for version 6.0 of the USP MMG. The USP MMG are composed of two organizational levels, USP Categories and USP Classes, which characterize the statutory requirement for Medicare Part D plan benefit design to include drugs from each category and class. The USP MMG includes a list of associated drug examples that aligns with the Part D drugs reflected on the Center for Medicare and Medicaid Services (CMS) Formulary Reference File.

Nine new USP Classes will be in version 6.0 of the USP MMG. Two of the USP Classes are nomenclature changes to reflect the therapeutics of the USP Classes. Six new USP Classes are created to accommodate new FDA approved drugs. The Glucocorticoids / Mineralocorticoids USP Class will be removed to broaden the Hormonal agents, Stimulant / Replacement / Modifying (Adrenal) USP Category to include Corticotropin. Nomenclature changes are occurring for the Respiratory Tract Agents USP Category and for five USP Classes.

4. Next Steps

Dr. Earnest explained the public comment period ends on October 31, 2013, and the timeline for the final deliverable to CMS.

5. Open Microphone Q&A Session

Lynda Bryant-Comstock (GSK) requested that USP evaluate the ***Blood Glucose Regulators Class***, and elevate some of the Pharmacotherapeutic Groups to official USP Classes. She cited the USP MMG v5.0 revision of the ***Cardiovascular Agents*** as precedent. Given the prevalence and significance of the diabetes issue in the United States, it is important to provide access to multiple classes of treatments for diabetes. Within the Medicare and dual eligible populations, 28% and 36% of the population are being treated for diabetes. The current USP MMG v6.0 structure is not granular enough to support the standard of care. GSK will be providing written comments.

James Russell (GSK) requested USP consider placing the combination drug Vilanterol in the ***Respiratory Tract Agents, Other*** USP Class. At the current time, the individual drug is listed however it is not available on the US market outside of the combination product. GSK will be providing written comments.

James Russell (GSK) requested moving Belimumab, currently in the ***Immune Suppressants*** USP Class to the ***Immunomodulators*** USP Class. GSK will be providing written comments.

Marlene Dressman (Vanda) requested USP include Tasimelteon, currently in FDA review, in the USP MMG. Vanda will be providing written comments.

Nicole Quon (Cubist Pharmaceuticals, formerly Optimer Pharmaceuticals) requested fidaxomicin (Dificid) be distinguished in its own USP Class, to separate it from the other macrolides. Cubist will be providing written comments.

Jason Bradt (Astellas) requested the USP consider placement of mirabegron in a new class, “Beta-3 Adrenergics”, similar to the USP MMG classification of opioids. He stated that

mirabegron is a first in class genitourinary agent with distinctive safety in elderly patients at risk for excessive anti-cholinergic load. He cited that the Medicare population has a significant incidence of OAB (over active bladder), and use of anticholinergics pose significant risk. He cited the recently published results from a VA Community Living Centers study, evaluating older adults (65 and older) living in long-term care facilities and the risk and benefits of bladder antimuscarinics (Moga, et al., 2013). The retrospective analysis of the Minimum Data Set (MDS) showed that the number-needed-to-treat to improve incontinence (NNT = 32, 95% CI 17–125) was on par with the number-needed-to-harm in the hip fracture analysis (NNH = 36, 95% CI 12–209). Dr. Bradt stated that the 'ratio of NNT to NNH was one", and suggested this evidence should be considered in providing placement for mirabegron. *(Note: this analysis did not include mirabegron, and was a retrospective analysis from October 1, 2002- September 2009; most patients were receiving immediate release oxybutynin. See Appendix A: Abstract.)* A member of the Expert Committee stated that this is substantially difficult patient population to treat and inquired about the availability of fall-risk data in this population for mirabegron. Astellas responded that they have pooled data from three placebo-controlled phase III studies for patients above 65 years of age; however, anti-cholinergic activity was not specifically studied. Astellas agreed to provide a summary of available evidence in their written comments.

Deborah Walter (Takeda) commented that the ***Antidepressants*** USP Category in v6.0 of the USP MMG has the same four USP Classes as v2.0 created in 2005. This USP Category is very crowded since there are new antidepressants. Ms. Walker recommends that USP consider dividing this USP Category into more distinct classes, and inquired about the purpose of the nomenclature change for the ***Serotonin/ Norepinephrine Reuptake Inhibitors***. An Expert Committee member commented that USP recognizes the increased number of antidepressants, and chose to broaden this USP Class to include other drugs. The Expert Committee deliberated about this class, and considered that the large NIMH STAR*D study demonstrated that these drugs are not dramatically different from one another. While there are clinical differences between patient responses, the data is lacking to determine which drug is best for a given case. Takeda will be providing written comments.

Debra Kronschnabel (ViiV Healthcare) asked USP to consider a sixth anti-retroviral USP Class for "CCR5 antagonists/ fusion inhibitors" or "Entry Inhibitors" instead of placement of these agents in the ***Anti-HIV Agents, Other USP*** Class. Over the next three years there are several new drugs expected to come into the US market. Ms. Kronschnabel discussed the need for patients to have access to HIV medications and the use of the USP MMG by payers in providing access. The rapid development of resistance seen with the HIV virus is also an important consideration in providing clinicians and patient's ready access to all agents identified in the HHS treatment guidelines (http://aidsinfo.nih.gov/guidelines). ViiV will be providing written comments.

Mihaela Munteanu (Teva) requested USP consider placing omacetaxine mepesuccinate (Synribo) in a unique USP Class due to its mechanism of action. Teva is working with the FDA to change the administration requirement to allow patient and care giver administration, which would create broader Medicare part D options. USP noted that at the current time, this drug is only dispensed in healthcare facilities and is not considered a Part D drug by CMS. Teva will be providing written comments.

Tom Reis (Alkermes) notified USP that Alkermes will be sending in written comments.

A commenter requested that the slides be made available to participants after this webinar concludes. USP confirmed that they would be posted on the USP website.

A commenter inquired about the criteria noted in the Guiding Principles, “scientifically valid and clinically relevant”, and asked how that was assessed for purposes of including combination drugs in USP MMGv6.0. An Expert Committee member replied that a scientifically valid reason is needed to combine two drugs into one dosage form, besides convenience. While the Expert Committee recognized the importance of patient adherence, the inclusion of combination drugs solely for that purpose would be better determined by sponsor plan P&T review. In order for a combination product to be on the USP MMG, it needs to offer a clinical solution that may not be possible through the single-ingredient dosage forms. USP staff added that when the FRF alignment occurs, any combination drug listed on the CMS Formulary Reference file is coded to the USP Category (and no USP Class).

A commenter noted that in one case, the inclusion of a newly FDA approved drug created a new class and USP relocated several drugs previously on v5.0 into that new class. The commenter inquired if that could be construed to mean that the new class was itself previously appropriate. USP staff responded that this was an unusual example, where there were antineoplastic drugs that were originally positioned outside of the ***Antineoplastics*** Category. The movement of the drugs into the ***Antineoplastics*** Category met practical needs of consolidating similar drugs, and moving them under the appropriate class of clinical concern.

6. Adjourn

USP staff appreciates the participant’s feedback at the meeting and is looking forward to reviewing the written comments.

The meeting adjourned at 3:45 p.m.

Table1: Public Participants (10/24/2013)

#	Name	Company
1	Adrianna Simonelli	Pharmaceutical Care Management Assoc.
2	Alexander Kraus	Grunenthal USA, Inc.
3	Amanda Seeff-Charny	Forest Labs
4	Andrew Zebrak	Boehringer Ingelheim
5	Ann Johnson	Pharmacy Healthcare Solutions, Inc.
6	Annemarie Wouters	Manatt Health Solutions
7	Bill Soucie	Xenoport, Inc
8	Brenna Jenny	Sidley
9	Brette McClellan	Alcon Laboratories
10	Bruce Kreter	Gilead Sciences
11	Carla McSpadden	Forest Research Institute
12	Carolyn Hickey	Alexion
13	Chris Piazza	Bayer
14	Courtney Keplinger	Novo Nordisk
15	Deborah Walter	Takeda
16	Debra Kronschnabel	ViiV Healthcare
17	Drew Saelens	Applied Policy
18	Elisabeth Daniel	Avalere Health
19	Emily Rath	Astellas Pharma US, Inc.
20	George Coutros	Sanofi
21	Giao Le	Cubist Pharmaceuticals
22	Gina Reckard	Astellas Scientific and Medical Affairs
23	Iris Tam	Genentech
24	James Osborne	GlaxoSmithKline
25	James Russell	GlaxoSmithKline
26	Jane Horvath	Merck
27	Jason Bradt	Astellas
28	Jennifer Snow	AstraZeneca
29	Jim Stansel	Sidley.com
30	John Carlsen	Covance
31	Josh Cohen	Avalere Health
32	Kara Sperandeo	Frx.com
33	Kate Holland	Vanda Pharmaceuticals
34	Kent McKinney	Allergan
35	Kevin O'Neill	Alkermes
36	Kim Hulsizer	Alcon Laboratories
37	Kristin Viswanathan	Biotechnology Industry Organization
38	Laurel Todd	Biotechnology Industry Organization
39	Lauren Buckley	Kimbell Associates

#	Name	Company
40	Lauren Hoffman	Express Scripts
41	Lynda Bryant-Comstock	GlaxoSmithKline
42	Marlene Dressman	Vanda Pharmaceuticals
43	Mary Jo Carden	Academy of Managed Care Pharmacy
44	Meghan Burris	The Herald Group
45	Mihaela Munteanu	Teva Oncology
46	Nicole Quon	Optimer Pharmaceuticals
47	Ravi Upadhyay	Genentech
48	Rob Haralson	The Herald Group
49	Robert Forman	Alkermes
50	Sarah Wells Kocsis	Amgen
51	Stephanie Hales	Sidley
52	Thomas Reis	Alkermes
53	Todd Edwards	GlaxoSmithKline
54	William Gittinger	Kimbell & Associates

APPENDIX A: JAMDA Web Abstract
Risks and Benefits of Bladder Antimuscarinics Among Elderly Residents of Veterans Affairs Community Living Centers

(Moga, D. C., Carnahan, R. M., Lund, B. C., Pendergast, J. F., Wallace, R. B., Torner, J. C., et al. (2013). Risks and Benefits of Bladder Antimuscarinics Among Elderly Residents of Veterans Affairs Community Living Centers. *JAMDA , 14* (10), 749-760.)

Objectives: To evaluate risks and benefits of bladder antimuscarinics (BAMs) among elderly long term care nursing home residents.

Design: Retrospective cohort study using a new user design and propensity score matching.

Setting: Veterans Affairs (VA) Community Living Centers (Nursing Homes).

Participants: Older adults (65 and older) admitted for long term care between October 1, 2002, and September 30, 2009.

Measurements: The study used multiple VA data sources (Minimum Data Set [MDS], inpatient, outpatient, and pharmacy prescriptions administrative files). The following outcomes were evaluated: (1) fractures (hip fracture and "any" fracture) identified from inpatient and/or outpatient data (ICD-9-CM codes) and from MDS; (2) cognitive performance measured using the validated MDS Cognitive Performance Scale; (3) improvement in urinary incontinence measured from MDS; (4) quality of life measured from MDS using 2 validated instruments: Index of Social Engagement and Health Status Index. Covariates included demographic characteristics, baseline continence status (bladder and bowel) and continence management, preexistent urinary tract infections, body mass index, comorbidities, other medication use, cognitive status, and mobility at baseline. These variables were used to calculate the predicted probability (propensity score) of being initiated on a BAM; the resulting propensity scores were used to match new users and nonusers. Outcomes were compared with Cox proportional hazards regression and generalized estimating equations methodology.

Results: BAMs were used by 9.8% of the residents 65 years and older admitted for long term care; 44% (1195) were new users. Of these, all but 53 received nonselective immediate release preparations, predominantly oxybutynin chloride (75%). BAM initiation resulted in improved urinary continence status (odds ratio = 1.27, 95% confidence interval [CI] 1.07–1.5) and better social engagement (difference in mean index of social engagement score = 0.2074, 95% CI 0.055–0.3598). The risk of fractures was significantly increased in new users as compared to nonusers (hip fracture: hazard ratio [HR] = 3.67, 95% CI 1.46–9.34; "any" fracture: HR = 2.64, 95% CI 1.37–5.10). The number needed to treat (NNT) to obtain improvement in urinary incontinence after 90 days of treatment (NNT = 32, 95% CI 17–125) was similar to the number needed to harm (NNH) at 90 days in the hip fracture analysis (NNH = 36, 95% CI 12–209). There were no differences in cognitive performance or overall quality of life scores associated with BAM use.

Conclusion: These results question the continued use of BAMs, particularly immediate-release oxybutynin chloride in elderly nursing home residents.

USP Medicare Model Guidelines v6.0
Open Microphone Web Meeting #4
Providers / Healthcare Associations
Friday, October 25, 2013
10:00 a.m. to 11:50 a.m. EDT
Teleconference

Chair: N. Jo Braden
Scientific Liaison: Jami Earnest
Expert Committee Manager: Ken Freebern

Notes

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Goals and Anticipated Outcomes

- To describe USP and the Expert Committee's role in developing and updating the USP Medicare Model Guidelines (USP MMG)
- To describe the major revisions proposed for USP MMG v6.0
- To solicit specific feedback from interested stakeholders on the structural content and organization of the USP MMG v6.0

Attendees

Expert Committee/Expert Panel Members

1. Jo Braden
2. Andrea Brassard

CMS Liaison
Marie Manteuffel

Public Participants
See Table #1 at the end of the notes

USP Staff
Shawn Becker, Jami Earnest, Ken Freebern

3. Introductions
Dr. Jami Earnest welcomed the group at 10:00 a.m. and described the process for the Open Microphone meeting. USP staff and Expert Committee members introduced themselves over the teleconference. Dr. Earnest explained that in order to ask questions or make comments during the meeting, participants must be connected to both the WebEx and audio portions. Questions will be collected using the WebEx Q&A process and will be addressed in order.

2. Background on USP Medicare Model Guidelines
Ms. Shawn Becker reviewed a presentation outlining the background of the U.S. Pharmacopeial Convention, the Council of Experts, the role of USP in creating public standards, and the Medicare Modernization Act of 2003.

3. USP Medicare Model Guidelines v6.0

Dr. Earnest outlined the Guiding Principles for version 6.0 of the USP MMG. The USP MMG are composed of two organizational levels, USP Categories and USP Classes, which characterize the statutory requirement for Medicare Part D plan benefit design to include drugs from each category and class. The USP MMG includes a list of associated drug examples that aligns with the Part D drugs reflected on the Center for Medicare and Medicaid Services (CMS) Formulary Reference File (FRF).

Nine new USP Classes will be in version 6.0 of the USP MMG. Two of the USP Classes are nomenclature changes to reflect the therapeutics of the USP Classes. Six new USP Classes are created to accommodate new FDA approved drugs. The Glucocorticoids / Mineralocorticoids USP Class will be removed to broaden the Hormonal agents, Stimulant / Replacement / Modifying (Adrenal) USP Category to include Corticotropin. Nomenclature changes are occurring for the Respiratory Tract Agents USP Category and for five USP Classes.

4. Next Steps

Dr. Earnest explained the public comment period ends on October 31, 2013, and the timeline for the final deliverable to CMS.

5. Open Microphone Q&A Session

Mark Levis (Johns Hopkins University) requested the USP consider moving the placement of omacetaxine mepesuccinate (Synribo) from the ***Antineoplastics, Other*** USP Class to a unique class for "Protein Synthesis Inhibitors" due to the recent FDA approval for chronic myelogenous leukemia (CML). He cited concerns for patient access and ability of staff to administratively manage access to omacetaxine mepesuccinate if plans instituted formulary management hurdles.

Phyllis Foxworth (Depression and Bipolar Support Alliance) suggested further defining the ***Antidepressants*** USP Category to include a new class since the ***Serotonin and/or Norepinephrine Modulators*** USP Class could be very limiting. She also expressed the need for USP to evaluate the ***Antidepressants, Other*** Class and to create new classes that are more descriptive.

Phillip Jennings and Carla McSpadden (Forest Research Institute) appreciated the revised nomenclature for the ***Phosphodiesterase Inhibitors, Airways Disease*** USP Class; however, they recommend a separate class for roflumilast as a "Selective PDE4 Inhibitors" since the mechanism of action is unique. Dr. McSpadden emphasized that Roflumilast is not a bronchodilator. She noted that the mechanism of action of theophylline was not as a PDE inhibitor (*Note: theophylline in not a selective PDE inhibitor*).

Russell Rosenberg (Atlanta Sleep) and Karl Doghramji (Jefferson Medical College) requested enhancing the Sleep Disorder Agents USP Category to include a Circadian Rhythm Disorders USP Class for the expected approval of tasimelteon.

Kara Sperandeo (Forest Research Institute) suggested three additional USP Classes for the three subtypes of ***Irritable Bowel Syndrome Agents*** in the ***Gastrointestinal Agents*** USP Category. She suggested "IBS- Constipation", "IBS- Diarrhea", and "Chronic Idiopathic Constipation". She cited that agents in these classes are not interchangeable. She suggested this division would aid in decision making processes and are consistent with the Rome III Criteria for IBS (http://www.romecriteria.org/criteria/).

Paul Doghramji (Collegeville Family Practice) requested USP consider dividing the ***Bronchodilators, Anticholinergic*** USP Class into two classes for "Long-acting agents" and for "Short-acting agents". This would be in accordance with the most recent GOLD Guidelines (http://www.goldcopd.org/Guidelines/guidelines-resources.html).

Travis Cooper (Forest Research Institute) requested maintaining the blank line between Ceftaroline fosamil and Cefepime in the ***Antibacterials*** Category to indicate Ceftaroline fosamil is the only FDA approved drug for *Methicillin-Resistant Staphylococcus aureus*.

Ian D'Souza (Forest Research Institute) commented that the ***Antidepressant, Serotonin and/or Norepinephrine Modulator*** Class is crowded.

Andrea Weddle (HIV Medicine Association) suggested more frequent updating of the list of associated drug examples in the USP MMG. Ms. Weddle requested that the combination drug Atripla be added to the example list, and cited the inclusion of Atripla in the HHS treatment guidelines (http://aidsinfo.nih.gov/guidelines). She supported the new ***Antivirals, Anti-HCV*** class and suggested that USP consider the newer agents entering the market in the next 1-2 years. The CMS liaison mentioned that CMS and the Center for Consumer Information and Insurance Oversight may have more frequent updates, especially for drugs used for critical diseases such as hepatitis, HIV, and oncology.

Rakesh Jain (Austin Texas) identified himself as a practitioner and researcher. He requested having separate class designations for SSRI and SNRI antidepressants to help indicate the mechanism of action is different. He expressed the concern that the current draft of the USP MMG ***Antidepressants*** Category 'lumps' too many distinctly different drugs together.

Mary Jo Carden (Academy of Managed Care Pharmacy) requested that the USP MMG should be aligned with the FRF and a complete list of RXCUI (RxNorm Concept Unique Identifier) needs to be maintained with associated Category and Class.

Wade Delk (American Society for Pain Management Nursing) suggested and will submit a written request to create a new USP Class for opioid analgesics with FDA recognized abuse deterrent characteristics.

Mary Kruczynski (Community Oncology Alliance) appreciated the new USP Class and the example drugs in the ***Antineoplastics*** USP Category; and inquired when it would be effective. In addition she inquired if all the new USP classes would be 'protected'. USP staff responded that the USP MMG will be delivered to the public in 2014 and is applicable to the 2015 and beyond plan years. The nine additional USP Classes to the previous v5.0 of the USP MMG are not automatically 'protected'. CMS responded that ***Antineoplastics*** are already protected by CMS regulations. CMS responded that the following six protected classes will remain the same: Immune Suppressants for organ transplants, Antidepressants, Antipsychotics, Anticonvulsants, Anti-HIV agents, Antineoplastics.

6. Adjourn

USP appreciates the participants' preparation, advocacy, and time to attend these Open Microphone teleconferences. The meeting adjourned at 11:50 a.m.

Table 1: Public Participants (10/25/2013)

#	Name	Company
1	Adrianna Simonelli	Pcal Care Mgmt Assoc
2	Amanda Seeff-Charny	Forest Labs
3	Andrea Weddle	HIV Medicine Association
4	Annemarie Wouters	Manatt Health Solutions
5	Brenna Jenny	Sidley
6	Bruce Kreter	Gilead Sciences
7	Carla McSpadden	Forest Research Institute
8	Catherine Brandon	Arnold & Porter LLP
9	Chris Piazza	Bayer
10	Deborah Walter	Takeda
11	Drew Saelens	Applied Policy
12	Elisabeth Daniel	Avalere Health LLC
13	Ian D'Souza	Forest Labs, Inc
14	James Russell	GlaxoSmithKline
15	Jane Horvath	Merck
16	John Carlsen	Covance
17	Kara Sperandeo	Forest Research Institute
18	Karl Doghramji, MD	Jefferson Medical College
19	Kimberly Miller	HIV Medicine Association
20	Krystalyn Weaver	NASPA
21	Lauren Hoffman	Express Scripts
22	Lynda Bryant-Comstock	GlaxoSmithKline
23	Mark Levis	Johns Hopkins University
24	Mary Jo Carden	Academy of Managed Care Pharmacy
25	Mary Kruczynski	Community Oncology Alliance
26	Meghan Burris	The Herald Group
27	Paul Doghramji, MD	Collegeville Family Practice
28	Phillip Jennings, Pharm.D.	Forest Labs
29	Phyllis Foxworth	Depression and Bipolar Support Alliance
30	Rakesh Jain	Not Given, Austin Texas
31	Rob Haralson	The Herald Group
32	Robert Fechtner	Rutgers NJ Medical School
33	Russell Rosenberg, Ph.D.	Atlanta Sleep
34	Stephanie Hales	Sidley
35	Travis Cooper	Forest Research
36	Vanessa Okeke	Corporate Council on Africa
37	Wade Delk	American Society for Pain Management Nursing

Appendix VIII: Public Comments

COMMENT ID	Topic	USP Category/ Class	Summary	USP Decision/ Rationale
10310034 10310042 10310044 10310056 10310059 10310061 10310072	Expand Categories	"Anti-Obesity Agents"	Seven (7) commenters suggested developing a new USP Category for Anti-Obesity treatments. Several commenters encourage the EC to consider the increased medical knowledge regarding obesity etiology and treatment. Also, commenters stated concern that the statutory interpretation of the treatment of obesity under 'lifestyle' drugs is no longer appropriate.	Comment not incorporated. This exceeds the authority of USP, as anti-obesity drugs are not Part-D eligible. Refer to Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.1.
10310042	Expand Categories	"Fertility Agents"	One (1) commenter suggested developing a new USP Category for Fertility drugs, especially in consideration of the EHB utilization of the USP MMG.	Comment not incorporated. This exceeds the authority of USP, as drugs are not Part-D eligible. Please refer to Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.1.
10310042 10310046 10310059	Expand Categories	"Oral Contraceptives"	Three (3) commenters suggested developing a new USP Category/Class for Oral Contraceptives. One commenter requested the development of 1 category, or 2 classes (oral and non-oral) under Hormonal Agents, Stimulant/ Replacement/ Modifying Sex Hormones. Commenters highlight that Medicare beneficiaries are under 65 y.o., and women of childbearing age should have access to full range. Commenters suggest that combination products be included in this classification.	Comment not incorporated. Drugs used for oral contraception are already listed on the USP Medicare Model Guidelines, and Combination Products are only listed by exceptions defined by the USP MMG Guiding Principles.
10240010 10290015 10310028 10310042 10310059 10310075	Expand Classes: Abuse Deterrent Formulations	***Analgesics, Opiate Analgesics (Short- and Long-acting)***	Six (6) commenters suggested developing a new USP Class for Abuse Deterrent Formulations of short- and long-acting opiate analgesics. Commenters cite the 2010 FDA Guidance and ONDCP 2011 report which are part of the federal strategy to reduce the public health burden of prescription drug abuse. One commenter suggests this action would fall within USP's authority , as "necessary to accommodate changes in therapeutic use."	Comment not incorporated. Insufficient clinical evidence and/or outcome data is available at this time to justify a new USP class.

10310036 10310038 10310040 10300023	Expand Classes	***Anti-Addiction/ Substance Abuse Treatment***	Four(4) commenters provided comments about the Opioid Dependence class. Three (3) commenters suggested further refinement of class to include short- and long-acting treatments, adjuvant treatments, and more pharmacologically distinct classes ; one (1) commenter requested retaining the USP MMG v5.0 'Opioid Antagonists' class. Commenters cited the current public health implications of prescription drug abuse and the Medicare Part D efforts in appropriate prescribing of opiates.	Comment not incorporated. Insufficient clinical evidence and/or outcome data is available at this time to further divide the classes.
10070002	Tobacco Cessation Medications	***Anti-Addiction/ Substance Abuse Treatment Agents, Smoking Cessation Agents***	One (1) commenter encouraged USP to follow the PHS Clinical Practice Guidelines (2008), approving all 7 FDA medications: Varenicline, bupropion, nicotrol inhaler, nicotine nasal spray, nicotine patch, nicotine lozenge, nicotine gum	USP acknowledges this comment, and notes that by USP MMG convention, "nicotine" in the example drug list refers to all five nicotine products. Therefore, all of the approved FDA medications available by prescription only are already included in the ***Smoking Cessation Agents*** class.
10310032	Drug-resistant TB	***Antibacterials***	One (1) commenter suggested that the antibacterial classes be reviewed to consider the needs of multiple drugs in the same classes and categories to treat Drug Resistant TB Treatment. Commenter suggested that under the current rules, the option for some plans to cover only one drug per class and category would clearly be a significant problem for treatment of drug resistant TB, an already difficult to treat airborne infectious disease with serious public health implications.	Comment not incorporated. The issue raided by this commenter is true of many infectious diseases and not unique to TB. The USP MMG support other P&T decision making processes which are better suited to ensure the antibiotic utilization as suggested by this commenter.
10310032	ceftaroline fosamil	***Antibacterials, Beta-lactam, Cephalosporins***	One (1) commenter supports the classification of ceftaroline fosamil in the Beta-lactam, Cephalosporins drug class.	USP acknowledges the supportive comment.
10310053	ceftaroline fosamil	***Antibacterials, Beta-lactam, Cephalosporins***	One (1) commenter suggested that USP differentiate the MRSA activity of ceftaroline fosamil, especially compared to cefepime HCl.	Comment not incorporated. The USP MMG does not differentiate antibiotics based on specific antimicrobial activity. The USP MMG support other P&T decision making processes which are better suited to ensure the antibiotic utilization as suggested by this commenter.

10310040 10310054	Tobramycin, Aztreonam	***Antibacterials, Inhaled Anti-infectives***	Two (2) commenters suggested retaining the previous placement of aztreonam and tobramycin, and not creating a new class.	Comment not incorporated. Inhaled anti-infectives were relocated from the ***Antibacterials*** Category to ***Respiratory Agents, Cystic Fibrosis Agents Class.***
10310054 10300021 10310059 10310065	Fidaxomicin	***Antibacterials, Macrolides***	Four (4) commenters suggested that fidaxomicin be recognized in a different class than with the other macrolides.	Comments not incorporated. The USP MMG does not differentiate antibiotics based on specific antimicrobial activity. The USP MMG support other P&T decision making processes which are better suited to ensure the appropriate antibiotic utilization as suggested by this commenter. Of note, FDA has also categorized this drug as a macrolide.
10310044 10310067	Expand Classes	***Anticonvulsants***	Two (2) commenters suggested expanding the anticonvulsant class to reflect different mechanisms of action, especially those drugs in the 'other' class. One (1) commenter suggested a class structure: 1. Voltage dependent sodium channel, fast and slow inactivation...2. Potassium channel...3.Calcium channels, high and low voltage...4. GABA modulation, a. Enhancement of GABA receptor function. Inhibition of GABA metabolism,c. Inhibition of GABA synaptic re-uptake..5. Glutamate receptors..6. Presynaptic vesicle modulation, 7. Anticonvulsant, Other	Comments not incorporated. At the current time, there is insufficient clinical evidence and/or outcome data to support further subdivision of this USP Class.
10070001	Drug name-spelling	***Anticonvulsants, Gamma-aminobutyric Acid (GABA) Augmenting Agents***	One(1) commenter suggested correcting the misspelling of 'clobam' to the correct spelling “clobazam”.	Comment incorporated.

10280013 10290016 10290017 10290018 10310030 10310042 10310048 10310059 10310064 10310074 10100003 10240011 10310030 10310074 10230008 10180007	Expand Classes	***Antidepressants***	Sixteen (16) commenters suggested that the Antidepressant classes should be expanded to reflect different mechanisms of actions, particular the ***Serotonin and/or Norepinephrine Modulators*** and ***Antidepressant, Other*** classes. Some commenters cite that the USP MMG ***Antidepressant*** Category has not been updated to reflect current therapeutic use of these agents, and has been unchanged since USP MMG v2.0. One commenter expressed concern that the classification systems will negatively impact patients, since over 50% of antidepressant scripts are written by primary care practitioners who may have their options limited. Some commenters are concerned about the 'unprotected' nature of this class in the EHB application of USP MMG.	Comments partially incorporated. USP has retained the previous USP MMG designation of SSRI/ SNRI. Evaluation of all drugs in the ***Antidepressant*** category resulted in reclassification of several agents from ***Antidepressants, Other*** into other established USP Classes. There is currently insufficient clinical evidence and/or outcome data to support more divided USP classes, or to adopt a "multimodal antidepressant" class .
10310064	Vortioxetine	***Antidepressants***	One (1) commenter suggested that USP may consider a 'multimodal antidepressants' class for the placement of vortioxetine, rather than ***Antidepressant, Other.***	Comment not incorporated. USP has retained the previous USP MMG designation of SSRI/ SNRI. Evaluation of all drugs in the ***Antidepressant*** category resulted in reclassification of several agents from ***Antidepressants, Other*** into other established USP Classes. There is currently insufficient clinical evidence and/or outcome data to support more divided USP classes, or to adopt a "multimodal antidepressant" class .
10310048	vilazodone	***Antidepressants, Serotonin and/or Norepinephrine Modulators***	One (1) commenter supports the USP's addition of vilazodone and levomilnacipran, and supported the nomenclature change to ***Serotonin and/or Norepinephrine Modulators*.**	USP acknowledges the supportive comment. USP has retained the previous USP MMG designation of ***SSRI/ SNRI.***

10290019	Diclegis--doxylamine and pyridoxine	***Antiemetics***	One (1) commenter suggested that USP review doxylamine succinate and pyridoxine hydrochloride (Diclegis) for inclusion in USP Medicare Model Guidelines v6., and to consider a new USP Class for Nausea & Vomiting of Pregnancy.	Comment not incorporated. USP evaluated Diclegis, and placed in USP Class ***Antiemetics, Other.***
10310040	Butoconazole	***Antifungals***	One (1) commenter requested clarification on the removal of butoconazole from USP MMG v6.0, citing the 2014 FRF does list the drug.	Comment incorporated. USP corrected the USP MMG Example Drug List.
10310032	bedaquiline	***Antimycobacterials, Antituberculars***	One (1) commenter supports the addition of bedaquiline to the ***Antituberculars*** drug class.	USP acknowledges the supportive comment.
10310063	EnzalutamideNew Class	***Antineoplastics***	One (1) commented supported the placement of enzalutamide and suggested refining the class to a new class, " *Antineoplastics, Androgen receptor inhibitor"* .	Comment not incorporated. USP retained the placement of enzalutamides within the ***Antiandrogens*** Class.
10310049	Expand Classes	***Antineoplastics***	One (1) commenter recommended that USP review the Antineoplastics category and revise class names to reflect tumor type treated rather than drug mechanism of action.	Comment not incorporated. USP acknowledges the comment, and recommends that the suggested taxonomy scheme would not have an effect on patient access in the Medicare Part D benefit, as the USP MMG are intended to support.
10310043 10310073	Omacetaxine	***Antineoplastics***	Two (2) commenters requested the inclusion of omacetaxine mepesuccinate) in the USP MMG v6.0. One commenter stated that the FDA is evaluating the administration by a healthcare professional, and that labeling may be removed.	Comment not incorporated. USP acknowledges these comments, and will review the revised FDA information is available. Currently omacetaxine is not Part-D eligible, and is outside of scope for USP MMG.
10310046	vorinostat	***Antineoplastics***	One (1) commenter requested vorinostat (Zolinza) to be reclassified from the ***Antifungal Agent*** category to the ***Antineoplastics***	USP acknowledges this comment, and has added vorinostat (Zolinza) to ***Antineoplastics, Other*** . The drug voriconazole is retained under ***Antifungals***.

10310045	radium Ra 223 dichloride	***Antineoplastics, Antineoplastics Other***	One (1) commenter requested USP add radium Ra 223 dichloride to USP MMG v6.0	Comment not incorporated. This request exceeds USP authority, as Radium 223 dichloride is not a Part D eligible drug.
10310029	vandetanib	***Antineoplastics, Molecular Target Inhibitors***	One (1) commenter supported USP inclusion of vandetanib in the USP MMG v6.0	USP acknowledges the supportive comment.
10310039	afatnib	***Antineoplastics, Molecular Target Inhibitors***	One (1) commenter supported USP's inclusion of linagliptin and afatinib in USP MMG v6.0	USP acknowledges the supportive comment .
10310045	regorafenib	***Antineoplastics, Molecular Target Inhibitors***	One (1) commenter supported USP's inclusion ofregorafenib in USP MMG v6.0	USP acknowledges the supportive comment .
10310060	Stribild, Complera	***Antivirals***	One (1) commenter supported Stribild placement in Integrase Inhibitors class, and Complera in the Non-Nucleoside Reverse Transcriptase Inhibitors class.	USP acknowledges the supportive comment.
10310040 10310054	boceprevir and telaprevir	***Antivirals, Anti-HCV Agents, NS3 Protease Inhibitors/Antihepatitis Agents***	Two (2) commenters were not supportive of the proposed Anti-HCV classes, and recommended that USP utilize the USP MMG v5.0 ***Antihepatitis Agents*** classification only.	Comments partially incorporated. USP has divided the antihepatitis drugs into two classes, ***Anti-hepatitis B (HBV) Agents*** and ***Anti-hepatitis C (HCV) Agents***
10310033 10310035 10310062	Expand Classes	***Antivirals, Anti-HCV Agents, NS3 Protease Inhibitors/Antihepatitis Agents***	Three (3) commenters were supportive of the proposed Anti-HCV Agents, and the effort to treat hepatitis B and hepatitis C by dividing the anti-hepatitis class into two classes,	Comments incorporated. USP has divided the antihepatitis drugs into two classes, ***Anti-hepatitis B (HBV) Agents*** and ***Anti-hepatitis C (HCV) Agents.***
10310027 10310033 10310035 10310062	Expand Classes, Hep B and Hep C	***Antivirals, Anti-HCV Agents, NS3 Protease Inhibitors/Antihepatitis Agents***	Four (4) commenters requested that USP review the anti-hepatitis drug classes in December, to accommodate new drug entries (sofosbuvir, simprevir) and consider expanding the anti-hepatitis class into two classes, anti-hepatitis B class and anti-hepatitis C .	Comments incorporated. USP has divided the antihepatitis drugs into two classes, ***Anti-hepatitis B (HBV) Agents*** and ***Anti-hepatitis C (HCV) Agents.***
10310035 10310042 10310059 10310033	Atripla	***Antivirals, Anti-HIV Agents, Integrase Inhibitors (INSTI)***	Four (4) commenters recommend the inclusion of Atripla	Comments incorporated. Atripla is included in the Part-D Example list.

10310033 10310035		***Antivirals, Anti-HIV Agents, Integrase Inhibitors (INSTI)***	Two (2) commenters support the proposed updates to the anti-HIV (antiretroviral) agent classes, including the new integrase inhibitor drug class (INSTI) and the additions to the "example" drug list.	USP acknowledges the supportive comment.
10310029	Expand Classes	***Bipolar Agents***	One (1) commenter recommended the current classification of the Bipolar Agents should be divided into three distinct pharmacologic classes: antimanic, antidepressant, and maintenance.	Comment not incorporated. There is insufficient clinical evidence and/or outcome data to support further dividing the classes.
10310042 10300024 10310037 10310049	Expand Classes	***Blood Glucose Regulators, Antidiabetic Agents***	Four (4) commenters suggested expansion of classes in Antidiabetic Agents. One commenter identified there are 23 drugs in one class which does not recognize the recent advances in the clinical and therapeutic management of diabetes. One commenter suggested division into five or more separate classes, consistent with the current USP Pharmacotherapeutic Groups.	Comments not incorporated. This USP Category is divided in a manner consistent with the use of the USP MMG. There is insufficient clinical evidence and/or outcome data to support further dividing the classes.
10310039	linagliptin	***Blood Glucose Regulators, Antidiabetic Agents***	One (1) commenter supported inclusion of linagliptin in the USP MMG v6.0	USP acknowledges the supportive comment.
10310029	ticagrelor	***Blood Products/ Modifiers/ Volume Expanders***	One (1) commenter supported inclusion of ticagrelor in the USP MMG v6.0	USP acknowledges the supportive comment
10310047 10310059	Expand Classes	***Blood Products/ Modifiers/ Volume Expanders, Anticoagulants***	Two (2) commenters requested the expansion of ***Anticoagulants.*** Both commenters suggested four new classes : Oral Direct Thrombin Inhibitors, Oral Direct Factor Xa Inhibitors, Indirect Fxa/FIIa Inhibitors, Vitamin K Antagonists.	Comments not incorporated. There is insufficient clinical evidence and/or outcome data to support further dividing the classes with respect to the use of these drugs with Medicare beneficiaries.
10310045	Expand Classes	***Blood Products/ Modifiers/ Volume Expanders, Blood Formation Modifiers***	One (1) commenter expressed concern that there is no USP Class for Factor VIII products.	Comment not incorporated. Per CMS regulations, Factor VIII products are not Part D eligible. Please refer to Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.1.

10310052	Expand Classes	***Blood Products/ Modifiers/ Volume Expanders, Blood Formation Modifiers***	One (1) commenter requested that ***Blood Formation Modifiers*** should be expanded based upon diseases and / or medical conditions.	Comment not incorporated.
10310040	mecamylamine	***Cardiovascular Agents, Cardiovascular Agents, Other***	One (1) commenter requested clarification on Mecamylamine, which is red texted and identified as a "new FDA approved drug, 3/19/2013" but is also crossed out (***Cardiovascular Agents, Other***). "	USP acknowledges the comment; USP will include mecamylamine on the MMG alignment on FRF, but it will not be listed as an example drug.
10310041	Gabapentin enacarbil	***Central Nervous System Agents, CNS Agents, Other***	One (1) commenter recommended to classify gabapentin enacarbil in a new class "alpha-2-delta ligands" within a new "Restless Legs Syndrome Agents" Category; and/or within ***Analgesics*** category. Commenter identifies that gabapentin enacarbil is one of four drugs FDA-approved to treat primary moderate-to-severe RLS.	Comment not incorporated. Gabapentin enacarbil was placed in ***Central Nervous System Agents--CNS, Other***
10310058	dalfampridine	***Central Nervous System Agents, Multiple Sclerosis Agents***	One (1) commenter recommended a new class should be developed for dalfampridine , "Multiple Sclerosis Agents: Potassium Channel Blockers" or " MS Agents, Other".	Comment not incorporated. Insufficient clinical evidence or outcome data to support development of a new USP Class.
10310076	Expand Classes	***Central Nervous System Agents, Multiple Sclerosis Agents***	One (1) commenter recommended that the class for multiple sclerosis agents is too broad to achieve the balance between patient access and plan flexibility, and suggested division of class to include consideration of routes of administration.	Comments not incorporated. There is insufficient clinical evidence and/or outcome data to support further dividing the classes with respect to the use of these drugs with Medicare beneficiaries.
10300022 10300025	Tasimelteon	***Central Nervous System Agents, Sleep Disorders***	Two (2) commenters requested placement for tasimelteon. One commenter suggested that a new class be created, and it would not be appropriate to classify under Sleep Disorders, others as non-24 is a circadian rhythm disorder, not a sleep disorder.	USP acknowledges comment, and will review drug when it is FDA approved.

10310052	New Class	***Dermatological Agents***	One (1) commenter recommended a new USP Class called "Dermatological Biologics- TNF Blockers" within the existing "Dermatological Agents"	Comment not incorporated. Insufficient clinical evidence and/or outcomes data to support duplicate placement of drugs for the intended use of the USP MMG. In the USP MMG, multiple classifications for drugs are exceptions defined by the Guiding Principles.
10310050	Expand Classes	***Gastrointestinal Agents, Irritable Bowel Syndrome***	One (1) commenter recommended division of the Irritable Bowel Syndrome class into three new classes: "Irritable Bowel Syndrome with Constipation Agents," "Irritable Bowel Syndrome with Diarrhea Agents," and "Chronic Idiopathic Constipation Agents." Commenter also opined that the Part D appeals process is insufficient to provide beneficiary access in situations when a plan does not cover a medically necessary prescribed drug.	Comment not incorporated. USP acknowledges the clinical distinctions and has reflected this comment in the infrastructure of the USP MMG which allows unofficial pharmacotherapeutic groups.
10310054 10310040	Lack of CMS support	***Gastrointestinal Agents, Short Bowel Syndrome Agents***	Two (2) commenters did not support the introduction of the new class, "Short Bowel Syndrome Agents." . One commenter recommended USP should reclassify somatropin back into the ***Hormonal Stimulant*** class, and place teduglutide and glutamine into the ***Gastrointestinal Agents, Other*** class.	Comments partially incorporated. USP has retained the Short Bowel Syndrome drugs under the ***Gastrointestinal Agents, Other.***
10240009 10310068 10310070	Mirabegron	***Genitourinary Agents, Antispasmodics, Urinary***	Three (3) commenters recommended that mirabegron be considered for a distinct class (Beta-3 Adrenergic Agonists) separated from anticholinergic drugs.	Comments not incorporated. Insufficient clinical evidence and/or outcome data to support development of a new USP Class with only one drug.
10310040	dutasteride, finasteride	***Hormonal Agents, Antiandrogens***	One (1) commenter recommended deleting the remaining ***Hormonal, Antiandrogen*** class , since Dutasteride and Finasteride are also listed in the ***Benign Prostatic Hypertrophy*** class.	Commented incorporated.
10300024	Expand Classes	***Hormonal Agents, Stimulant/ Replacement/ Modifying (Pituitary) Category***	One (1) commenter recommended expansion of ***Hormonal Agents, Stimulant/ Replacement/ Modifying (Pituitary) Category***.	Comment not incorporated. Insufficient clinical evidence or outcome data provided for category expansion.

10120004 10120005	Example Drug: Inclusion of Thyrogen	***Hormonal Agents, Stimulant/ Replacement/ Modifying (Thyroid)***	Two (2) commenters requested the inclusion of thyrotropin alpha (recombinant human TSH; brand name Thyrogen) to the approved list of agents shown in USP MMG v6.0.	Comment not incorporated. Per CMS regulations, Thyrogen is not a Part D eligible drug. Refer to Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.1.
10240012	Belimumab (Benlysta)	***Immunological Agents***	One (1) commenter recommended reclassifying belimumab as an ***Immunomodulator*** rather than ***Immune Suppressant***	Comment incorporated. Benlysta reclassified as ***Immunomodulator.***
10310052	New Class	***Immunological Agents***	One (1) commenter recommended a new USP Class called "Immune Suppressants - TNF Blockers" within the existing "Immunological Agents"	Comment not incorporated. TNF-blockers are currently classified on the USP MMG, and duplicate listing is not necessary by Guiding Principles.
10310057	New Class	***Immunological Agents***	One (1) commenter recommended more granularity in the categories and classes relevant to plasma protein therapies, and new classes for "Intravenous Immune Globulin Therapies" and "Subcutaneous Immune Globulin Therapies".	Comment not incorporated. Insufficient clinical evidence and/or outcomes data to support duplicate placement of drugs for the intended use of the USP MMG. In the USP MMG, multiple classifications for drugs are exceptions defined by the Guiding Principles.
10310057		***Immunological Agents***	One (1) commenter supported USP for including important plasma protein therapies in ***Immunological Agents***	USP acknowledges the supportive comment.
10310071 10310042	Angioedema Agents	***Immunological Agents, Angioedema (HAE) Agents***	Two (2) commenters suggested "Angioedema (HAE) Agents" should be divided into two classes: 1. "Hereditary Angioedema Agents, Acute" 2. "Hereditary Angioedema Agents, Prophylaxis". One (1) commenter recommended the proposed "Angioedema (HAE) Agents" should be renamed "Hereditary Angioedema Agents" .	Comments not incorporated. There in insufficient evidence to support the further division of this class with respect to Medicare beneficiaries.
10310040	icatribant, C1-Esterase	***Immunological Agents, Angioedema (HAE) Agents***	One (1) commenter did not support the new "Angioedema (HAE) Agents" , and recommended that these drugs be categorized within an existing, higher level grouping such as ***Immunomodulators.***	Comment not incorporated.

10310042 10310047 10310059 10310032	Expand Classes	***Immunological Agents, Immune Suppressants***	Four (4) commenters recommended that Immune Suppressants be restructured to separate the 'protected class' from other agents. One commenter suggested a division into four areas: "post-transplant, biological disease modifying antirheumatic drugs (DMARDs), non-biological DMARDs, and other therapies". One commenter suggested a division into five areas:" Post-Transplant, DMARDS, Nonbiologic DMARDs, TNF Inhibitors, Other". Another commenter suggested that the post-transplant class should also be subdivided, given that under current rules, patient access to these medically necessary drugs may be denied by some health plans that only cover two drugs per class.	Comments not incorporated.
10310052	New Class		One (1) commenter recommended a new USP Class called "RANK Ligand Inhibitors" within the existing ***Metabolic Bone Disease Agents.***	Comment not incorporated.
10310042	"Vascular Endothelial Growth Factor" Class	***Ophthalmic Agents***	One (1) commenter recommended a new class for the vascular endothelial growth factor (VEGF) products that have approved indications to treat the most serious causes of blindness.	Comment not incorporated. Anti-VEGF Agents are all intravitreal injections, and currently outside of scope for USP MMG classification of Part D eligible drugs. Refer to Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.1.
10310069	Combination Product/ Ophthalmic products	***Ophthalmic Agents***	One (1) commenter recommended a new class in the ***Ophthalmic Agents*** called ***"***Ophthalmic Non-Beta Blocker Fixed Combination".	Comment not incorporated. Combination Products are only listed by exception as defined by the USP MMG Guiding Principles. Insufficient clinical evidence and/or outcomes data to support creating a new USP class.
10310055 10300026	aclidinium	***Respiratory Tract/ Pulmonary Agents***	Two (2) commenters recommended creating separate classes, "Bronchodilators, Long-Acting Anticholinergic" and "Bronchodilators, Short-Acting Anticholinergic " (LAMA/SAMA)	Comments not incorporated.
10310029	Combination products/ ICS/LABA	***Respiratory Tract/ Pulmonary Agents***	One (1) commenter recommended the inclusion of combination products, "Inhaled Corticosteroids (ICSs)/ Long-acting beta2-adrenergic agonist (LABAs),"	Comment incorporated. ICS/LABAs are included in the ***Respiratory Tract, Others*** class.

10300026 10310049	Combination products/ vilanterol	***Respiratory Tract/ Pulmonary Agents***	Two (2) commenters recommended including the combination product with vilanterol (BreoEllipta) as combination therapy in the ***Respiratory Tract Agent, Other,*** rather than listing vilanterol as a single drug	Comment incorporated.
10310042	Combination/ COPD drugs	***Respiratory Tract/ Pulmonary Agents***	One (1) commenter recommended combination drugs are an important part of COPD treatment regimens, and should be included in USP MMG v6.0.	Comment incorporated. ICS/LABAs are included in the ***Respiratory Tract, Others*** class.
10310057	New Class	***Respiratory Tract/ Pulmonary Agents***	One (1) commenter recommended a new class for "Alpha-1 Agents" to be comprised of the multiple alpha-1 proteinase inhibitor (human) products indicated to treat alpha-1 deficiency.	Comment not incorporated.
10310032	Roflumilast	***Respiratory Tract/ Pulmonary Agents***	One (1) commenter supported the change in category nomenclature from: "Bronchodilators, Phosphodiesterase Inhibitors (Xanthines)" to "Phosphodiesterase Inhibitors, Airways Disease." "intent of the space [in the MMG] is to recognize the drugs unique mechanism of action from other PDE inhibitors, then we support the spacing."	USP acknowledges the supportive comment.
10310051 10300026	Roflumilast	***Respiratory Tract/ Pulmonary Agents***	Two (2) commenters recommended that USP create a new class entitled "Selective Phospho diesterase – 4 (PDE– 4) Inhibitors" within the R***espiratory Tract Agents/ Pulmonary Tract Agents.***	Comments not incorporated. Insufficient clinical evidence and/or outcome data to support development of a new USP Class with only one drug.
10310057		***Respiratory Tract/ Pulmonary Agents***	One (1) commenter supports USP for including plasma protein therapies in ***Respiratory Tract / Pulmonary Agents***	USP acknowledges the supportive comment
10310032	aclidinium	***Respiratory Tract/ Pulmonary Agents, Bronchodilators, Anticholinergic***	One (1) commenter supported the addition of aclidinium to ***Bronchodilators, Anticholinergic*** .	USP acknowledges the supportive comment.

10310032	indacaterol	***Respiratory Tract/ Pulmonary Agents, Bronchodilators, Sympathomimetics***	One (1) commenter supported the addition of indacaterol to the list of ***Bronchodilators, Sympathomimetic.***	USP acknowledges the supportive comment.
10290014 10310032 10310040	Ivacaftor	***Respiratory Tract/ Pulmonary Agents, Cystic Fibrosis Agents***	Three (3) commenters support the new class "Cystic Fibrosis Agents". One commenter recommends the class be called "CFTR Potentiators" to prevent a class that groups potentiators and correctors together. One commenter suggests maintaining the broad category, and include the two "inhaled anti-infectives" (tobramycin and aztreonam) and Dornase Alfa (Pulmozyme).	Comments partially incorporated. Insufficient evidence to support a new class for "CFTR Potentiators". Comment incorporated regarding relocation of anti-infectives into the ***Cystic Fibrosis Agents*** class.
10310054	Lack of CMS support	***Respiratory Tract/ Pulmonary Agents, Cystic Fibrosis Agents***	One (1) commenter does not support the new class "Cystic Fibrosis Agents "and suggests reversion to MMG (Version 1.0) Mucolytic class, which would offer a wider array of applications for various diagnoses.	Comment not incorporated. Current treatments for cystic fibrosis are not appropriately classified as mucolytics. ***Cystic Fibrosis Agents c***lass was expanded to include other additional drug specifically approved for treatment of patients with CF (e.g., inhaled anti-infectives).
10310032 10310045	macitentan, riociguat (New FDA Approvals)	***Respiratory Tract/ Pulmonary Agents, Pulmonary Antihypertensives***	Two (2) commenters recommend adding macitentan and riociguat to the list of ***Pulmonary Antihypertensives***	Comments incorporated.
10310039	Combination Product/ Combivent Respimat	***Respiratory Tract/ Pulmonary Agents, Respiratory Tract, Other***	One (1) commenter recommended Combivent Respimat placement should be in ***Respiratory Tract Agents, Other***	Comment not incorporated. The MMG does not specify delivery devices.

10310049	Umeclidinium Bromide and Vilanterol Trifenatate	***Respiratory Tract/ Pulmonary Agents, Respiratory Tract, Other***	One (1) commenter recommended placement of Umeclidinium Bromide and Vilanterol Trifenatate (currently under NDA review with FDA) in ***Respiratory Tract, Other***	Comment not incorporated. This product was not FDA approved during the revision timeline for USP MMG v6.0 which concluded Decmber 17, 2013.
10310049	Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine	***Vaccines***	One (1) commenter recommended requested placement of specific vaccine in Model Guidelines.	USP acknowledges this comment; vaccines will be added to the example list during the FRF alignment.
10300022	General--Appeals		One (1) commenter opined that beneficiaries should not be forced to rely on Part D appeals process to gain access to medically necessary drugs.	USP acknowledges these comments and will forward concern to CMS. This is outside the scope of the USP revision process.
10310040	General--Classes with 1 or 2 products		One (1) commenter opposed all of the new classes recommended in the USP MMG v6.0 (other than benzodiazepines). The commenter recommended USP to consider all of the implications, including beyond Medicare, when it proposes to establish a class with only one or two drugs in the Medicare Model Guidelines.	Comment not incorporated.
10310040	General--Combination Products		One (1) commenter opposed combination products to be listed within USP Version 6.0., citing the lack of scientific or clinical basis for new classes to be created specifically for combination products.	Comment not incorporated. By Guiding Principle, combination products may be included in the USP MMG for scientifically valid and clinically meaningful patient care issues.
10310042 10310049 10310059	General--Combination Products		Three (3) commenters recommend that Guiding Principles should be adopted to allow combination products in USP MMG, and transparent guidance can be provided for 'scientifically valid and clinically meaningful' definitions.	USP acknowledges these comments.
10310040	General--Designation of Medicare Model Guidelines		One (1) commenter supported the clear designation that the Model Guidelines are in fact the “Medicare” Model Guidelines.	USP acknowledges this supportive comment.

10310042 10310052	General-- Expand classes		Two (2) commenters recommended more granularity and comprehensiveness within and across the categories and classes of the USP MMG to ensure that the Model Guidelines include the spectrum of therapies needed by a Medicare population with diverse health needs. One commenter highlighted the need for increased granularity in the non-protected classes.	USP acknowledges this comment.
10310029	General-- Extended Release Products		One (1) commenter recommended extended release products be included on the associated drug list .	Comment not incorporated. Special dosage forms generally are not considered for individual inclusion in the USP Medicare Model Guidelines associated drug list.
10310059 10310052 10310047	General-- Medical Benefit Drugs (Part B)		Three (3) commenters recommended clarification on Medical Benefit Drugs and listing as sample drugs and/or FRF alignment with the USP MMG. One commenter encouraged USP to be consistent in excluding these drugs when they are clearly not available as Part D, and to err on the side of inclusion if there is a question regarding the coverage status.	USP acknowledges these comments. Part B and D status is situationally defined by CMS. The example list is a guide, and does not infer Part D coverage.
10300020	General- Policy Issues		One (1) commenter recommended linking the categories and classes to RxNorm Concept Unique Identifier (RxCUI) , and updating as new medications become available for Medicare Part D coverage. Commenter requested that USP provide transparency for determinations related to single medication classes.	USP acknowledges this comment. The USP MMG v6.0 will be aligned with the CY14 CMS FRF, which lists RxCUI. This will be maintained on the USP Website for the Medicare Model Guidelines.

10300022 10310027 10310033 10310035 10310042 10310044 10310045 10310047 10310049 10310052 10310057 10310059 10310072 10310076	General-- Revision Frequency		Fourteen (14) commenters recommended that the USP MMG be updated at least on an annual basis. One commenter recommended transparency and public comment process on the FRF alignment.	USP acknowledges these comments and will forward to CMS.
10310042	General-- Utilization management		One (1) commenter recommended USP should urge CMS to limit the potential for UM techniques, particularly on therapies within the protected classes.	USP acknowledges this comment and will forward to CMS.
10310066	General-- Medicare focus/ Beer's List		One (1) commenter recommended that USP tailor the guidelines to the Medicare population only. Commenter cited the Pharmacy Quality Alliance (PQA) High Risk Medication (HRM) list per American Geriatric Society recommendations to the Beer's List, and used USP to omit these medications from the USP MMG v6.0 or to work with CMS to exclude these drugs from the "two drug per therapeutic category/pharmacologic class" formulary requirement.	USP acknowledges this comment; Medicare population includes all ages, not just beneficiaries >65 y.o. . USP will forward comments to CMS.

10310027 10310031 10310033 10310035 10310040 10310042 10310044 10310045 10310047 10310049 10310052 10310057 10310059 10310061 10310072 10310076	General-- Utilization of the USP-MMG in the Essential Health Benefits (EHB)		Twenty-two (22) comments from sixteen (16) commenters provided input on the USP MMG utilization in the Affordable Care Act.	USP acknowledges these comments and will forward to CMS-Center for Consumer *Information and Insurance Oversight (CCIIO*)

Appendix IX: USP Background

The United States Pharmacopeial Convention (USP), established by practitioners in 1820, is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. USP's standards are also recognized and used in many other countries outside the United States. These standards have been helping to ensure good pharmaceutical care for people throughout the world for more than 185 years.

USP is an independent, science-based public health organization. As a self-sustaining not-for-profit, 501(c)(3) organization, USP is funded through revenues from the sale of products and services that help to ensure good pharmaceutical care. USP's contributions to public health are enriched by the participation and oversight of expert volunteers representing pharmacy, medicine, and other healthcare professions as well as academia, government, the pharmaceutical industry, health plans, and consumer organizations.

The USP Convention membership is constituted to ensure suitable representation of those sectors of the healthcare system that are impacted by, and in turn impact, USP's activities. The Convention can have more than 450 members representing:

- US colleges and schools of medicine and pharmacy.
- State medical societies and pharmacy associations.
- National and state professional and scientific organizations.
- Governmental bodies.
- Health science and other non-US organizations and pharmacopeias.
- Domestic, foreign, and international manufacturers, distributors, and trade and affiliated associations.
- Consumer organizations and persons representing the public interest.

Convention members elect the USP Convention Officers (president, treasurer, and secretary), the Board of Trustees, and the Council of Experts and vote on resolutions that determine the organization's direction and priorities.

The Council of Experts is the body that makes USP's scientific and standards-setting decisions. Members of the council are elected by the USP Convention membership. Each Council of Experts member serves as the chair of an Expert Committee for a five-year term, with the members of each Expert Committee also serving a five-year term. The Council of Experts and its Expert Committees provide the scientific foundation for USP's public health products and programs.