



**2005–2010 Medicare Model Guidelines Expert Committee (MGEC)
Meeting #11
Monday, August 6, 2007
Bethesda Marriott, Bethesda, Maryland**

Expert Committee Meeting Summary

Goals and Anticipated Outcomes

- To discuss CMS's formulary review process, the application of the Model Guidelines in managed care, legislative initiatives, and strategic drug information processes
- To discuss rules for expanding or collapsing categories, classes, or FKDTs
- To determine which new drugs will be included in the Model Guidelines
- To approve revisions to the Model Guidelines
- To review the timeline for the delivery of the Model Guidelines Version 4.0

Opening and Procedural Matters

Welcome and Call Meeting to Order

After establishing that a quorum was present, the meeting was called to order. The attendees introduced themselves.

New Rules of the Model Guidelines Expert Committee (MGEC)

It was proposed that the rules and procedures of the MGEC be changed to recognize the USP Chief Science Officer as the Chair. This proposal was unanimously adopted.

Approval of Minutes of the Previous Meeting

The minutes of the previous meeting, which was held on April 17, 2007, were reviewed and approved.

Review and Approval of the Agenda

The meeting agenda was reviewed and approved.

Conflict of Interest (COI)

- To improve the ability to proactively identify conflicts, rules pertaining to COI and the COI form are being revised. The revised rules will enable Chairs to view the forms. The current rules permit only staff to view the forms.
- Although Members of the Council of Experts (CoE) and Expert Committees (ECs) are not required to sign new forms annually (only to update them on an as-needed basis), they will be asked to complete and sign the revised form this fall.
- A new COI Certification form will be circulated at the beginning of each EC meeting to give Members increased opportunity to consider and disclose potential conflicts in regard to the topics to be discussed during the meeting.

Discussion

- Each Member will be asked to list anything that could interfere or have the appearance of interfering with their ability to vote objectively and impartially. If a Member consults with respect to a particular drug, that drug should be listed. There is no need to list all of the drugs manufactured by a company.
- If a Member is a consultant on a drug under a confidential arrangement, the Member could request permission from the manufacturer to disclose the drug name only to USP, or declare a conflict during a meeting without explaining why. The goal is to establish a connection to the drug at issue so that any conflict can be appropriately addressed.
- The definition of what constitutes a conflict is deliberately broad; e.g., if a Member feels strongly about the drugs being taken by a relative who is a Medicare Part D beneficiary, this could constitute a conflict and should be declared.
- The Centers for Medicare and Medicaid Services (CMS's) regulation on grants for a federal program includes standards for COI.

- Each MGEC Member should bring the best independent expertise to the process with a goal of transparency. If a conflict arises, it should be brought before the MGEC so that it can be dealt with openly and honestly. When a Member has a conflict, he or she must abstain from final deliberations and voting on that issue.
- Common sense should prevail.

CMS's Formulary Review Process

- Formulary review consists of three main elements: 1) elimination of discrimination, 2) robustness and broadness of formularies, and 3) innovation and flexibility to give beneficiaries access to drugs.
- In 2007, 78% of plans used the Model Guidelines (MGs). Even formularies based on another classification system are compared to the MGs to ensure that they cover at least two drugs for each category and class. The MGs comparison is one of 15 checks used to review formularies.
- The Formulary Reference File (FRF) is the universe of drugs used to build formularies.
- Most formularies include four tiers – generic, preferred, non-preferred, and specialty.
- When a category or class with only one or two drugs is created in the MGs, plans are required to include the drugs to meet the two-drugs-per-category/class requirement. This can constrain drug plans' negotiations with manufacturers to decrease costs.

Discussion

- The number of drugs covered by plans increased in 2007. The number of participating drug plans will increase in the 2008 benefit year.
- There are two types of formulary maintenance: 1) Positive changes offering the beneficiary more drugs, and 2) negative changes in which drugs are removed from the formulary or in which there are tiering changes (e.g., moving a brand name drug from a preferred to non-preferred tier when a new generic is approved). Negative changes require CMS approval.
- In 2007, there was a dramatic increase in negative non-maintenance change requests. If a plan has not submitted a good quality formulary for initial review, the change may not be accomplished during the plan year.
- Prior to 2007, CMS accepted clinical justification for the exclusion of FKDTs from a formulary. In 2007, more of these justifications were received and CMS's workload increased. In 2008, FKDTs will be used as an outlier test for the following reasons: 1) they are duplicative – the majority of FKDTs are already being accounted for in other formulary checks; 2) to allow flexibility for negotiation; and 3) Pharmacy and Therapeutics (P&T) committees have decision-making authority to determine which FKDTs are most appropriate for the population served by their plans.
- Feedback on the utilization of FKDTs by plans could assist MGEC decision-making. FKDTs were created to protect beneficiaries and enhance the nondiscriminatory practices of plans. Data may be available after CMS completes the outlier reviews of the 2008 formularies.
- The plans are aware of the FKDT outlier test and have an incentive to comply to avoid delays in formulary acceptance. CMS conducts the FKDT outlier test after all other checks have been completed, looking for formularies that are not in line with the majority of others.
- Drug plans often utilize tiering structures to accommodate high-cost drugs.

Recommendations for Future Versions of the Model Guidelines

- Maintain stability in the MGs and FKDTs. MGs V1.0 and 2.0 were similar. Major modifications were made in V3.0, causing CMS to re-evaluate its review process.
- Make the MGs easy to understand. Category and class names are what beneficiaries see in the marketing materials. Plans use parentheses [e.g. (blood pressure medication)] to help the beneficiaries. The MGEC could make the parentheses a part of the MGs.
- Elimination of drugs that are not covered under Part D. There was improvement in this area in MG V3.0. If an infused drug is used in a long-term nursing home setting, it may be considered a Part D drug. If it is used only in an acute care setting as part of a medical procedure, it will not be covered under Part D.
- Elimination of pre-1962 wrap-up drugs. Drugs that were on the market prior to 1962 can stay on the market if they have not changed. However, the FDA has determined that there are no pre-1962 drugs on the market that are unchanged. No time should be spent deliberating pre-1962 drugs.
- Consideration of combination products. Each drug moiety should be considered separately. The decision to include combination drugs on formularies should be left to the P&T committees.



- Elimination of single-drug classes. A pharmacologic class should not contain a single drug. In this situation, the drug should be accommodated at the category level or in an “other” class.

Discussion

- There was concern about coverage of intravenous drugs in patients who are asked to “brown bag” their medications to be administered in a rural doctor’s office. CMS has not received complaints regarding lack of coverage of these medications.
- Approximately 50% of the feedback received by CMS has been from advocate groups and 50% has been from plans.
- It was suggested that when a new drug with a unique mechanism of action is approved, it should be included in an “other” class.
- The MGs do not dictate or deny coverage. That is the responsibility of P&T committees.

Application of the Model Guidelines in Managed Care

Attendees were presented with information on formulary development under Medicare Part D.

- In 2006, plans thought that use of the MGs was required and were not aware that CMS would review other aspects of formularies, in addition to the classification systems they were modeled after.
- Plans are gravitating toward use of three and four tiers. A few plans have open formularies. Five-tier formularies usually include a separate tier for injectables. There is at least one seven-tier formulary.
- Thirty percent of plans used their own classification systems to avoid the need for additional operational staff and cost. From a marketing perspective, classification systems with broader categories are easier to explain to patients and physicians. These systems give drug plans the advantage of negotiating contracts with drug manufacturers.
- The MGs were used by newer, smaller plans that often used contractors for formulary management.
- There is a software product that links drugs and their NDC codes to the corresponding category and class in the MGs. It was used by a number of plans to populate their formularies.

Discussion

- The MGs still help fulfill the unique medication needs of the Medicare population.
- Decreasing granularity in the MGs will give drug plans more flexibility while maintaining clinical quality.
- There is a perception among some constituencies that pharmaceutical manufacturers have too much influence in getting their drugs included in the MGs. However, they realize that lobbying USP for inclusion of their drugs is not permitted.
- Formularies based on classification systems that are less granular than the MGs have been judged by CMS to offer the same protection as the MGs because each drug is reviewed individually, whether the formulary structure is granular or broad. If a drug has merit, how it is classified is not as important. In addition to the other formulary checks, the MGs are the standard by which all formularies are evaluated.
- Neither the names of the plans that use the MGs nor the other classification systems being utilized can be disclosed by CMS.
- The reduction in the percentage of plans using the MGs (74% in 2006, 60% in 2007) could be due to the way the data were reported. In 2006, plans indicated whether or not they were using the MGs. In 2007, whether or not the MGs were used was determined by CMS during the formulary review process.
- Some of the larger drug plans are submitting multiple formularies based on the various products they offer to Medicare beneficiaries.
- USP’s goal of protecting beneficiaries is being met.
- It was suggested that USP emphasize the value of the safe harbor provided by the MGs.

Legislative Initiatives: Drug Information

The attendees were presented with information on some of USP’s interests in healthcare reform.

- The Congressional Budget Office projected e-prescribing could result in a \$1.5 billion savings over the next five years. E-prescribing could be incorporated into the State Children’s Health Insurance Program (SCHIP) bill.
- There is a broader debate about the need to move toward value-based purchasing, an alternative to regulation in which business controls costs. Comparative effectiveness legislation has passed the House of Representatives.



- Health plans, consumers, and labor have been coming together to support broad healthcare reform. The fundamentalist religious community also is supporting it. Bipartisan relationships on congressional committees may make change possible in 2009.
- The Prescription Drug User Fee Act (PDUFA) reauthorization must be passed by the end of September 2007. Although follow-on biologics may not be included, the issue may be brought forward in a freestanding bill.
- USP could provide information as to why well managed formularies are superior to open-ended formularies.

Discussion

- The driver of comparative efficacy has been the purchaser community's interest in obtaining information about drugs to inform the development of well managed, clinically-based formularies. USP is doing this with the MGs. Comparative effectiveness data could assist MGEC decision-making.
- The MGEC has the opportunity to help improve the quality of prescribing for older adults and others covered by Medicare by providing evidence-based recommendations for use of drugs in older adults. USP could evaluate research data and perform drug-to-drug comparisons. Both prescribers and drug plans might benefit from this activity.
- A Senate committee developed an agreement providing a regulatory and legal pathway for qualified follow-on biologics that provided a 12-year period of exclusivity. However, close reading of the language revealed "ever-greening", whereby modest modifications to a brand name drug could enable another 12-year period of exclusivity, pushing out competition. Purchasers asked for clarifying legislative language. Work was not concluded before summer recess, so the issue could be reopened in the fall.
- *Senior Pharmacist* has created a preferred list of drugs for the elderly based on safety and efficacy information. USP could organize known information and be an unbiased source of generic drug information.
- USP may play a role in ensuring that follow-on biologics are interchangeable with comparable innovator products.
- Legislators need to be educated about the need for formularies, which enable provision of better care and enhance the information given to physicians as to the best drugs for particular diagnoses. USP should be more public on this issue. Medicare has overpaid through direct negotiation for Part B drugs.
- USP should have enhanced confidence in purchasers and should not include drugs in the MGs just because a drug company requests it.
- Use of a formulary can result in savings. The Veterans Administration (VA) obtains the lowest price for the drugs on its formulary. It does not cover every drug, but many physicians train in VA centers and become accustomed to prescribing certain drugs.
- The MGs include categories and classes for all Part D-eligible drugs that can be prescribed, not making decisions as to quality of care.

Drug Information: Strategic Discussion

The attendees were updated on recent developments regarding potential future healthcare information activities.

Rules for Collapsing or Expanding Categories, Classes, and Formulary Key Drug Types

The question of when to collapse and when to expand categories and classes has been debated since the development of the MGs V1.0. With increased granularity, the cost to plans and consumers increases. Less granularity can be obtained by collapsing groups into broader categories. However, stability of the MGs is important.

- Analysis of data on the use of the MGs by plans would facilitate modification of the MGs to ensure that they continue to be relevant to the marketplace. Data on appeals also would be useful.
- The MGEC's independence and market forces were discussed.
- The increasing number of FKDTs is a concern.

Review of New FDA-approved Part D-eligible Drugs/Submissions and Committee Recommendations

The MGEC reviewed and voted on the recommendations of the Information ECs for placement of the following drug products:

- Aliskiren hemifumarate tablets
- Deferasirox tablets (for oral suspension)
- Eculizumab injection
- Lapatinib ditosylate tablets
- Lisdexamfetamine dimesylate capsules



- Protein C concentrate (human) for injection
- Retapamulin ointment
- Rotigotine transdermal system

Review of Timeline for Delivery of Model Guidelines Version 4.0

- The status of action items from the previous meeting was reviewed.
- August 31, 2007 is the quarterly deadline for parties to submit information to be considered by the MGEC at the next meeting, on or about October 1, 2007.
- Although the timeline for the MGs V4.0 will not change, the deadline for the delivery of the MGs V5.0 could be earlier than February 2009 (perhaps December 2008) to enable CMS to publish guidances after release of the MGs.
- Attendees expressed concern about the compressed timeline, especially the time in which to review public comments. Although the deadlines are established by contract, staff will work to ensure the process includes ample time for reviewing comments received.

Adjournment

Attendees were thanked for a productive meeting, and it was adjourned.

