

finalized, we assigned therapeutic class codes and sorted each drug into therapeutic classes. We accomplished this by using an enhanced classification tool made available from First DataBank. The First DataBank Enhanced Therapeutic Classification System (ETC)<sup>3</sup> provides a method for classifying drugs and drug products into classes and sub-classes using a parent-to-child relationship hierarchy. Using a combination of identifiers and formulation-based and name-based drug concepts, the system provides for maximum flexibility and allows for categorization of drugs into more than

<sup>3</sup> According to First DataBank, the following sources were used in the compilation of data for the ETC: American Hospital Formulary Service (AHFS) Drug Information, Pharmacotherapy: A Pathophysiologic Approach, Martindale: The Extra Pharmacopeia, Applied Therapeutics: The Clinical Use of Drugs, Goodman and Gilman's The Pharmacological Basis of Therapeutics, Harrison's Principals of Internal Medicine, The Merck Manual of Diagnosis and Therapy, Current Medical Diagnosis and Treatment, The Merck Index, and manufacturer package inserts.

one therapeutic classification as necessary. The drugs were assigned to therapeutic categories and sub-categories based on National Drug Code and/or drug short name. The classification tool was then used to sort the listing of commonly used drugs according to therapeutic categories and sub-categories. The category list then underwent the following steps:

- It was reviewed for major therapeutic classes that did not appear in the listing. In addition, non-covered discount card drugs were eliminated and drugs covered under Part B were flagged.
- The revised draft classification and sub-classification system was reviewed by a pharmacy team, external to CMS, consisting of 5 PhD and clinical pharmacists, and two geriatricians/internists, to determine the level of specificity required to ensure that the types of medications required by Medicare beneficiaries are represented. The category list was also compared

with several commercial formulary categorization schemes.

- Several non-CMS internal medicine physicians with specialties in geriatrics and several non-CMS specialists with expertise in serving Medicare beneficiaries, reviewed the specifications and drugs listed to ensure that the category list represents types of drugs that are commonly needed by the Medicare population, and to provide the guidance concerning the drugs they routinely prescribe to Medicare beneficiaries in their areas of specialization, for the consideration of sponsors in their development of formularies for the Medicare drug discount card program. A total of 11 physicians took part in this review process.

- CMS clinicians, including 2 pharmacists and a physician, conducted a final review of the categories. We then finalized the categories based on this input.

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