Question: Can Part D plans include over-the-counter products (OTCs) as part of administrative expenses since they may provide significant cost savings as part of a utilization management program?

Answer: CMS understands that health plans and pharmacy benefit managers currently provide targeted coverage of over-the-counter medications (OTCs) in the commercial market as part of their cost-reduction strategies. OTCs -- many of which (e.g. Prilosec OTC® and Claritin®) were available by prescription when first marketed -- offer significantly cheaper alternatives to branded prescription medications, and often work just as well for most patients. The MMA does not allow Medicare plans to include OTCs as part of their drug benefit or supplemental coverage. As an incremental extension of the 2006 policy, for the 2007 benefit coverage year, CMS will allow Medicare plans the option to provide this alternative as part of their administrative cost structure without limitation to approved step therapy protocols since other OTCs play a role by substituting for prescription drugs as part of an overall drug utilization management strategy (e.g. OTC non-steroidal anti-inflammatory drugs). Having the plan process OTC purchases at the pharmacy under the Part D contract improves safety by allowing the prescription drug plan to access and include information on OTC utilization in its drug utilization review editing.

CMS will continue to review and approve plans' specific OTC protocols shown to provide safe, effective and less costly alternatives. While the potential cost savings associated with using certain OTCs is significant, CMS does not believe many OTC products will offer such savings. In certain situations, OTCs may be included as part of a step-therapy program, but this is no longer required. However, if a plan includes OTC products as a part of its utilization management program other than within step-therapy algorithms, the plan may not prior authorize or otherwise limit dispensing of formulary alternatives on the basis of prior usage of the OTC product.

Without exception OTCs included as part of a cost-effective drug utilization management program must still be provided to the beneficiary without any direct cost-sharing at the point of sale (costs would be included in administrative portion of the bid and, thus, ultimately reflected in premiums).

As we stated in the 2006 OTC guidance, since CMS will limit OTCs to those shown to provide safe, effective and less costly alternatives to formulary drugs, and since plans are not obligated to include OTC products within their utilization management programs, Medicare beneficiaries should not expect broad inclusion of OTCs under the Part D benefit. Similarly, States should not interpret this as justification to discontinue coverage for OTCs under Medicaid Programs. Plans choosing to include OTC products within their utilization management programs must understand and be prepared to appropriately educate their enrollees on the difference between OTCs provided as administrative costs as opposed to covered part D drugs. While beneficiaries will (and must) enjoy zero direct cost-sharing on these OTCs, they will also not have the same beneficiary protections required to ensure appropriate access to part D drugs. For example, if a plan changes its utilization management program to substitute one OTC agent for another, beneficiaries would not have meaningful transition supplies or exceptions or appeals options to remain on the original OTC agent. (This does not affect enrollees' ability to pursue an exception or appeal of step therapy requirements in favor of a part D drug).