DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR BENEFICIARY CHOICES

Date: December 5, 2006

Memorandum to: All Part D Sponsors

Subject: Clarification of LTE DESI Drugs and Oral Anti-Cancer Agents

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

Since we published the draft version of Chapter 6 of the Part D manual in September 2006, Part D Sponsors have reviewed their processes in relation to our proposed guidance. Consequently, we have received a number of comments and inquiries related to FDA's Less-than-effective Drug Efficacy Study Implementation (LTE DESI) drugs and Oral Anti-Cancer Agents covered under Part B. While we are continuing to finalize Chapter 6, we want to address these specific topics to assist Part D Sponsors. To that end we have included two questions and answers with this memorandum that articulate our policy and approach.

For questions on this policy please contact Gregory Dill at (312) 353-1754. For questions on PDE submissions please contact Merri-Ellen James (410) 786-4462.

Part D and DESI Drugs

Q: Which DESI drugs do not satisfy the definition of a Part D drug?

A: For a drug to be available for reimbursement by a Part D Sponsor it must meet the definition of a Part D drug. Section 1860D–2(e)(1) of the Social Security Act (the Act) generally defines a Part D drug to include those drugs that may be dispensed only upon a prescription and that meet the requirements of section 1927(k)(2) of the Act. Section 1927(k)(2) generally requires that the drug be approved by the FDA or is otherwise described under sections 1927(k)(2)(A)(ii) or (A)(iii) of the Act. These provisions address those drugs affected by the Drug Amendments of 1962 (amending the Federal Food, Drug & Cosmetic Act), which require that a new drug be proven effective, as well as safe. FDA's Drug Efficacy Study Implementation (DESI) evaluates the effectiveness of those drugs that had been previously approved on safety grounds alone. FDA indicates that these drugs, and those identical, related, and similar to them, may continue to be marketed until the administrative proceedings evaluating their effectiveness have been concluded, at which point continued marketing is permitted only if a new drug application (NDA or ANDA) is approved. The vast majority of the DESI proceedings have been concluded, but a few are still pending.

The definition of a Part D drug does not include less than effective (LTE) DESI drugs or those identical, related or similar drugs to the LTE DESI drug. Such drugs are identified by having a DESI indicator code of either 5 or 6. Part D Plans may find the following Medicaid lists as useful guidance in determining which DESI drugs have been determined to be less than effective: www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/desi.pdf and http://www.cms.hhs.gov/MedicaidDrugRebateProgram/09_DrugProdData.asp#TopOfPage. We are aware of other drug reference lists, First Data Bank/Medi-Span, etc, and that also contain LTE DESI information and should be consulted when appropriate to ensure that the definition of a Part D drug is satisfied. Where discrepancies occur between these lists, we recommend Sponsors consult with FDA's drug information center for verification of DESI status at 1-888-FDA-INFO, 301-827-4570 or http://www.fda.gov/cder/comment/commentdrug.htm.

As FDA continues to undertake reviews under the DESI program and announces results of its hearings, we would expect Part D Sponsors to adjust their formularies accordingly, as they should with any other applicable FDA drug product announcement. Our 2007 formulary reference file is in line with available DESI information. If a plan discovers the presence of any DESI 5 or 6's (i.e., LTE DESIs) on its 2007 formulary based an FDA announcement or otherwise, it should remove these drugs from the formularies, delete any PDEs previously submitted for these drugs, and make appropriate deductions to TrOOP and gross drug spend. No funds received under the Part D program may be used to pay for LTE DESI drugs.

We understand that some Part D Sponsors relied upon the USP classification system or USP drug list table that resulted in formulary inclusion of LTE DESI products. Based on this reliance, we will allow those LTE DESI products that were listed on the 2006 USP Model Guidelines or Categories and Classes or Drug List Table and were maintained on a Part D Sponsor's 2006 formulary, to be covered as Part D Drugs in Contract Year 2006. We have included a list of these

LTE DESI drugs in Appendix 1. We note that, up to this point, we have maintained a PDE filter that has rejected any LTE DESI PDE submissions. To facilitate resubmission of previously submitted LTE DESI products, we will be opening the PDE filter. We will announce this resubmission window at later date, but plans should prepare for this activity in the interim.

This LTE DESI policy will become effective February 1, 2007, to allow those beneficiaries who have been taking any of the LTE DESI drugs contained in Appendix 1, a transition supply in January 2007. Such a transition will afford the beneficiary sufficient time to move to a covered Part D drug, if the Part D Sponsor is not able to transition beneficiaries prior to January 1, 2007. We will also be providing a standardized letter that Part D plans can use to notify beneficiaries who have been taking LTE DESI products.

Part D and Oral Anti-Cancer Agents

Q:
Are oral anti-cancer agents with no indications other than cancer treatment eligible for reimbursement as Part D drugs, since the CMS Part D formulary guidance requires "all or substantially" of the antineoplastic classes?

A:
In the majority of cases, no. Whether a Part B covered* oral anti-cancer drug (i.e., capecitabine) is eligible for reimbursement under Part D depends upon any circumstances where there are any indications other than cancer treatment. We want to reiterate our Medicare Part B versus Part D Coverage Issues guidance, issued July 27, 2005, in which we stated that "to the extent that a Part B-covered oral anti-cancer drug has no other medically accepted indication besides cancer treatment, Part D plans should not include these drugs on their formularies. . . [F]or the drugs that have other medically accepted indications, prior authorization programs or other mechanisms to obtain diagnostic information could be used to ensure appropriate payment." For 2007, we remind Part D Sponsors that covered Part B oral anti-cancer agents with no indications other than cancer are also not to be covered through the plans exceptions process. Only if these drugs obtain an FDA label indication or an indication listed in one of the three statutorily mandated compendia (American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and DRUGDEX Information System) for something other than anti-cancer would they become eligible for reimbursement under Part D.

We understand that some Part D Sponsors relied upon the USP classification system or USP drug list table that resulted in formulary inclusion of covered Part B oral anti-cancer agents. Those Part D Sponsors with oral anti-cancer agents that were inappropriately maintained on Part D formularies (i.e., capecitabine) will be allowed to continue to cover these agents for the remainder of Contract Year 2006. Since our PDE filter did not reject any PDEs for oral anti-cancer agents, Part D Sponsors will not need to retrospectively resubmit any PDEs and may continue to submit new claims for the remainder of 2006.

* In general Part B would allow the reimbursement of an oral anti-cancer agent only if there is an equivalent injectable version; however, some oral anti-cancer agents are pro-drugs of injectable products and are also eligible for reimbursement under Part B. To facilitate a better understanding of the Part B rules regarding oral anti-cancer agents we provide the following link to our Part B policy:

http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=5057&lcd_version=23&show=all

Appendix 1
List of LTE DESI drugs available for Part D reimbursement in 2006 and January 2007

NDC	Product_Name		
00087054301	VASODILAN		
00087054401	VASODILAN		
00182139601	TRIMETHOBENZAMIDE HYDROCHLORIDE 250MG CAPSULES		
00182142719	T-GEN 200MG SUPPOSITORIES		
00182142723	T-GEN 200MG SUPPOSITORIES		
00182703811	HYDROCORTISONE ACETATE HEMORRHOIDAL 25MG SUPPOSITORIES		
00182703816	HYDROCORTISONE ACETATE HEMORRHOIDAL 25MG SUPPOSITORIES		
00245011112	HEMRIL-HC		
00245011212	HEMRIL 30		
00245011224	HEMRIL 30		
00472051112	HEMORRHOIDAL HC SUPPOSITORIES 25 MG		
00472051124	HEMORRHOIDAL HC SUPPOSITORIES 25 MG		
00496071603	PRAMOSONE CREAM 1%		
00496071604	PRAMOSONE CREAM 1%		
00496071703	PRAMOSONE CREAM 2.5%		
00496071704	PRAMOSONE CREAM 2.5%		
00496072604	PRAMOSONE LOTION 2.5%		
00496072606	PRAMOSONE LOTION 2.5%		
00496072903	PRAMOSONE LOTION 1%		
00496072904	PRAMOSONE LOTION 1%		
00496072906	PRAMOSONE LOTION 1%		
00496076304	PRAMOSONE OINTMENT 1%		
00496077704	PRAMOSONE OINTMENT 2.5%		
00496080004	ANALPRAM HC CREAM 2.5%		
00496080064	ANALPRAM HC 2.5% CREAM SINGLES		
00574709012	HYDROCORTISONE ACETATE SUPPOSITORIES 25 MG 12 UD		
00574709312	ENCORT		
00574722010	TRIMETHOBENZAMIDE SUPPOSITORIES		
00574722210	TRIMETHOBENZAMIDE SUPPOSITORIES		
00574722250	TRIMETHOBENZAMIDE SUPPOSITORIES 200 MG 50 UD		
00603812711	HEMORRHOIDAL HC SUPP		
00603812718	HEMORRHOIDAL HC		
00713010709	TRIMETHOBENZAMIDE HCL 100MG SUPPOSITORY		
00713010809	TRIMETHOBENZAMIDE HCL 200MG SUPPOSITORY		
00713010850	TRIMETHOBENZAMIDE HCL 200MG SUPPOSITORY		
00713050301	HYDROCORTISONE ACETATE 25MG SUPPOSITORY		
00713050312	HYDROCORTISONE ACETATE 25MG SUPPOSITORY		
00713050324	HYDROCORTISONE ACETATE 25MG SUPPOSITORY		
00781184001	ISOXSUPRINE 10MG	100.00 TB	1
00781184201	ISOXSUPRINE 20MG	100.00 TB	1
00904016012	HYDROCORTISONE ACETATE		
00904016060	HYDROCORTISONE ACETATE		
00904063560	VOXSUPRINE		
00904063660	VOXSUPRINE		

00904273515	TEGAMIDE 100MG SUPP
00904273615	TEGAMIDE 200MG SUPP
45802072332	TRIMETHO 100MG (CHLD) 50'S
45802072390	TRIMETHO SUPP 100MG CHILD
45802072432	TRIMETH 200MG SUP (ADULT) 50'S
45802072490	TRIMETH 200 MG SUP (ADULT) 10'S
45802072530	HC ACETATE SUPP 25MG
45802072531	HC ACETATE SUPP 25 MG
52152000902	ISOXSUPRINE TAB 10MG(100)
52152000905	ISOXSUPRINE HCL 10MG
52152001002	ISOXSUPRINE TAB 20MG(100)
52152001005	ISOXSUPRINE HCL 20MG
52152016602	TRIMETHOBENZAMIDE CAPSULES 250 MG
58177003704	TRIMETHOBENZAMIDE HCI
61570030361	ANUSOL-HC SUPPOSITORIES
61570030362	ANUSOL-HC SUPPOSITORIES
61570050410	TIGAN SUPPOSITORIES
61570050450	TIGAN 200MG SUPPOSITORIES
63304040812	PROCTOSOL HC 25MG SUPPOSITORIES x 12
63304040824	PROCTOSOL HC 25MG SUPPOSITORIES x 24
65649041112	ANUSOL-HC 25MG SUPPOSITORY 12'S
65649041124	ANUSOL-HC 25MG SUPPOSITORY 24'S
65649051112	PROCTOCORT 30MG SUPPOSITORY 12'S
65649051124	PROCTOCORT 30MG SUPPOSITORY 24'S
68040070426	NOVACORT