

April 6, 2005

Montana Medicaid Notice

Pharmacy and Home Infusion Therapy Providers

Heparin Flush Syringes - Coverage Issues

Effective Immediately

In recent months the Centers for Medicare and Medicaid Services informed states about certain heparin flush syringes that are not drugs under the Medicaid Drug Rebate Program. The determination of covered outpatient drugs under the Medicaid Drug Rebate Program generally depends on whether the drug has been approved as a prescription drug by the FDA under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act. While the FDA approved certain heparin flush syringes as prescription drugs under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act, others were issued device approvals. Those that were issued device approvals do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are therefore not eligible for Medicaid coverage under the Drug Rebate Program.

Those manufacturers participating in the Medicaid Drug Rebate Program that have received FDA approval under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act for their heparin syringes are:

- Hospira (labeler code 00409)
- Abbott (labeler code 00074)
- American Pharmaceutical Partners (labeler code 63323)
- Baxter Health Care (labeler code 00338 and 00641)

DESI Drugs

The Department received a fax from CMS dated April 6 2005 concerning the incorrect DESI status of the following products:

00496-0716 Pramosone Cream 1%
00496-0717 Pramosone Cream 2.5%
00496-0726 Pramosone Lotion 2.5%
00496-0729 Pramosone Lotion 1%
00496-0763 Pramosone Ointment 1%
00496-0777 Pramosone Ointment 2.5%

Although the labeler of these products provided a DESI Code 2 (safe & effective) for each NDC, the FDA has determined that these drugs are less than effective, or DESI Code 5.

Please be aware that these drugs will no longer be covered under Montana Medicaid as soon as First DataBank updates its drug file to reflect this change.

To offer some background, a program was established under which the Food and Drug Administration (FDA) would review the effectiveness of drugs and was named the Drug Efficacy Study Implementation (DESI) program. If the DESI review indicates a lack of substantial evidence of a drug's effectiveness for all of its labeled indications, the FDA will publish a Notice of Opportunity for a Hearing (NOOH) in the Federal Register concerning its proposal to withdraw approval of the drug for marketing. At that time, a manufacturer of that drug or identical, related or similar (IRS) drugs has the opportunity to request a hearing and provide the FDA with documentation of the effectiveness of the drug product before a final determination is made. Drugs for which a NOOH has been published are referred to as less-than-effective (LTE) drugs.

The Administrative Rules of Montana dictate that the Department will not participate in the payment of prescription drugs, which the Secretary of the Health and Human Services has determined, the prescription drug or its generic equivalent, to be less than effective for all conditions of use prescribed, recommended or suggested in the drug's labeling.

Contact Information

Any questions regarding this notice can be directed to Dan Peterson at (406) 444-2738 or the Medicaid Drug Prior Authorization Unit at (406) 443-6002.

For claims questions or additional information, contact Provider Relations:

Provider Relations in Helena and out-of-state: (406) 442-1837

In-state toll-free: 1-800-624-3958

Visit the Provider Information website:

<http://www.mtmedicaid.org>