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Suboxone, Subutex, and Buprenorphine Prior Authorization

Effective with date of service January 3, 2011, prior authorization requests for Suboxone (buprenorphine/naloxone), Subutex (buprenorphine) or generic buprenorphine will not be approved for doses greater than 24 mg (buprenorphine) per day. The maximum FDA-approved dose for buprenorphine is 24 mg per day. Doses higher than this have not been demonstrated to provide any clinical advantage. DMA clinical pharmacists have been working with prescribers to help transition their patients to the FDA approved dose since this prior authorization was implemented on September 15, 2010. The criteria for approval of Suboxone, Subutex or buprenorphine are posted on the following website: <http://www.ncmedicaidpbm.com>

Removal of Active Pharmaceutical Ingredients and Excipients as Covered Outpatient Drugs

CMS has provided policy clarification regarding the inclusion of active pharmaceutical ingredients (APIs) and excipients in the drug rebate program. An API is a bulk drug substance, which is defined by the Food and Drug Administration (FDA) as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient of the drug product [21 CFR § 207.3(a)(4)]. APIs may be included in extemporaneously compounded prescriptions and may serve as the active drug component in a compounded formulation.

In accordance with the foregoing, APIs do not meet the definition of a covered outpatient drug as defined in section 1927(k)(2) of the Social Security Act (Act). As such, APIs are not subject to the requirements of the Medicaid Drug Rebate (MDR) program. In addition, excipient products used in compounds (e.g., aquaphor, petrolatum, etc) are non-drug products and, as a result, should not be reported to the MDR program.

To the extent possible, CMS has identified the APIs and excipients that are listed in the MDR system. CMS is notifying manufacturers that the National Drug Codes (NDCs) do not qualify as covered outpatient drugs and, as a result, will be deleted from the MDR product file of covered outpatient drugs effective January 1, 2011. CMS will notify all State Medicaid programs regarding the removal of these products. The list of identified API and excipient NDCs can be found on the Policy & Reimbursement's Spotlight Webpage http://www.cms.gov/Reimbursement/02_Spotlight.asp#TopOfPage. Please note that this is not a definitive list.

The compounding powders and other products listed on the CMS website will not be rebate eligible effective January 1, 2011 and therefore will no longer be covered in the Medicaid Outpatient Pharmacy Program. However, some of the compounding powders and other products such as hydroxyprogesterone caproate, Flolan diluent, other diluents and baclofen will be covered in other program areas. Additional information will be provided in future updates.

Discontinuation of Focused Risk Management Program

DMA will discontinue the Focused Risk Management (FORM) program as of December 15, 2010. The FORM review will no longer be required, and pharmacies will no longer receive the professional service fee related to this program. Recipients aged 21 years and older who require more than 11 unduplicated prescriptions each month will continue to be restricted to a single pharmacy through the Recipient Opt-in program.

Incomplete Application Final Notice

As the provider enrollment, verification, and credentialing (EVC) vendor for the N.C. Medicaid Program, CSC processes enrollment applications, enrollment additions, and Medicaid Provider Change Forms. When an EVC credentialing coordinator determines that an application is missing information, the coordinator suspends the application as “Incomplete” and sends a letter to the applicant indicating the information that must be provided in order to complete the application. If the missing information is not provided within 30 days from the date of the letter, CSC sends a system-generated e-mail to the applicant (see below) stating that the application will be voided. Any applicant who feels that he/she has received this notice in error should immediately contact the CSC EVC Call Center at 1-866-844-1113. CSC will promptly investigate and address your concerns.

The following paragraph is excerpted from the e-mail message that CSC sends to an applicant when an application is voided because CSC has not received all of the required information within 30 days.

After reviewing your application, an EVC Credentialing Coordinator determined that the information provided was incomplete. CSC sent notification to your office via mail and/or e-mail of the necessary corrections to complete your request for enrollment. As of the date of this letter, the records indicate that it has been more than thirty (30) days since CSC notified you of the necessary correction(s), and we have not received a response from you. Therefore, your application will be voided as an inactive, incomplete application for enrollment. There will be instances where the application is completed in processing but the follow-up status of Incomplete was not removed. Please contact CSC for verification and investigation.

If you have questions regarding the notice, please contact the CSC EVC Call Center (1-866-844-1113) and reference the Enrollment Tracking Number (ETN) indicated in the final notice.

Customer service agents are available Monday through Friday, 8:00 a.m. through 5:00 p.m. Eastern Time, at 1-866-844-1113.

Enrollment Fee Reminders

As mandated by Session Law 2009-451, beginning September 1, 2009, the N.C. Medicaid Program implemented a \$100 enrollment fee for all new enrollments and at 3-year intervals when providers are re-credentialed.

APPLICANTS SHOULD NOT SUBMIT PAYMENT WITH THEIR APPLICATION.

Upon receipt of your enrollment application, an invoice will be mailed to you if the fee is owed. An invoice will only be issued if the tax identification number in the enrollment application does not identify the applicant as a currently enrolled Medicaid provider.

Providers are reminded that payment

- is due immediately upon receipt of an invoice for the enrollment fee;
- should be remitted to the address on the invoice and not directly to CSC; and
- is accepted by check or money order made payable to DMA.

Please make every effort to remit payment promptly. Applications will not be processed if payment is not received. If payment is not received within 30 days of the date on the invoice, your application will be voided and you will be required to reapply.

Changes in Drug Rebate Manufacturers

The following changes have been made in manufacturers with Drug Rebate Agreements. It is listed by manufacturer's code, which are the first five digits of the NDC.

Addition

The following labelers have entered into a Drug Rebate Agreement and have joined the rebate program effective on the date indicated below:

<i>Code</i>	<i>Manufacturer</i>	<i>Date</i>
27808	Tris Pharm, Inc	11/30/2010
52276	Orphan – Europe, Sarl	12/15/2010

Voluntarily Terminated Labeler

The following labelers have requested voluntary termination effective April 1, 2011:

Rosemont Pharmaceuticals, Ltd	(Labeler 13632)
Oncology Therapeutics Network Joint Vent	(Labeler 15210)
American Red Cross	(Labeler 52769)
Digestive Care, Inc	(Labeler 59767)
Synthon Pharmaceuticals, Inc	(Labeler 63672)
Cebert Pharmaceuticals, Inc	(Labeler 64019)
Avanir Pharmaceuticals, Inc	(Labeler 64597)
Genzyme Corporation	(Labeler 64894)
Azur Pharma	(Labeler 68322)

Checkwrite Schedule

December 02, 2010	January 11, 2010
December 07, 2010	January 19, 2010
December 14, 2010	January 27, 2010
December 22, 2010	

Electronic Cut-Off Schedule

November 24, 2010	January 06, 2010
December 02, 2010	January 13, 2010
December 09, 2010	January 20, 2010
December 16, 2010	

Electronic claims must be transmitted and completed by 5:00 p.m. on the cut-off date to be included in the next checkwrite. Any claims transmitted after 5:00 p.m. will be processed on the second checkwrite following the transmission date. POS Claims must be transmitted and completed by 12:00 midnight on the day of the electronic cut-off date to be included in the next checkwrite.

Lisa Weeks, PharmD, R.Ph
Chief, Pharmacy and Ancillary Services
Division of Medical Assistance
Department of Health and Human Services

Glenda Adams, PharmD.
Outpatient Pharmacy Program Manager
Division of Medical Assistance
Department of Health and Human Services

Craigan L. Gray, MD., MBA., JD
Director
Division of Medical Assistance
Department of Health and Human Services

Ann Slade, R.Ph.
Chief, Pharmacy Review Section
Division of Medical Assistance
Department of Health and Human Services

Sharon H. Greeson, R.Ph.
Pharmacy Director
HP Enterprise Services

Melissa Robinson
Executive Director
HP Enterprise Services
