
OKlahoma Health Care Authority

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Drug Utilization Review for Oklahoma Medicaid

Plavix® (clopidogrel) Utilization in the Medicaid Fee-for-Service Population

Clopidogrel is a platelet aggregation inhibitor that was approved for use by the FDA in November 1997 for the reduction of atherosclerotic events as follows: recent MI, recent stroke, and established peripheral arterial disease. Recently clopidogrel was also approved for use in acute coronary syndrome (unstable angina/non-Q-wave MI). There are other off-label uses for clopidogrel, however, the only ones with strong clinical support in the primary literature are as an adjunct to aspirin after coronary stent implantation, use with or without dalteparin to promote healing of refractory stasis ulcers, and to reduce the risk of recurrent stroke or other vascular events in patients that have experienced a transient ischemic attack.

Despite a popular view that clopidogrel is a medication with few side effects, it does have some adverse reactions that deserve mentioning. The major adverse reactions seen with clopidogrel are bleeding, abdominal pain, vomiting, dyspepsia, gastritis, upper respiratory infections, flu-like syndromes, and chest pain. Thrombotic thrombocytopenic purpura (TTP), while a rare reaction, has been reported even after a short exposure of less than 2 weeks. Clopidogrel



is contraindicated in those patients that have active pathological bleeding such as peptic ulcers or intracranial hemorrhage, and in patients with coagulation disorders.

Clopidogrel can interfere with the metabolism of phenytoin, tamoxifen, torsemide, fluvastatin and some NSAIDs. The use of clopidogrel with naproxen has shown an increase in occult blood loss. In a recent study published in *Circulation* (2003;107:32-7), ator-

vastatin produced a dose-dependant inhibition of clopidogrel activity. In this very small study, the 40mg/day dosage of atorvastatin significantly to completely attenuated the antiplatelet activity of clopidogrel.

A review of clopidogrel utilization in the Oklahoma Medicaid fee-for-service population revealed that clopidogrel usage has been increasing an average of 55% each year for the past two years. Oklahoma Medicaid spent over \$3.5 million on this drug during the past fiscal year to treat 5,930 clients. The average cost of clopidogrel per claim was \$108.17; and the cost per day was \$3.29. The peak incidence of clopidogrel use was seen in clients 50-95 years of age.

When the medical claims data was reviewed for diagnoses, only thirty-six percent of the utilization was for FDA approved indications. If off-label uses with strong clinical support are included, then the appropriate usage of clopidogrel in

creases to approximately forty-one percent. The remaining fifty-nine percent of the utilization was for a wide variety of diagnoses such as hypertension, senile psychosis, depressive disorders, diabetes, etc.

Plavix Prior Authorization

As a result of an emergency action by OHCA to assist in balancing the budget, Plavix was added to the list of medications that require prior authorization for Medicaid fee-for-service and SoonerCare Choice clients. The criteria are subject to change on or before July 1, 2003.

For authorization, a client must meet one of the following diagnostic criteria and have failed aspirin therapy (due to either side effects or event recurrence), or have a documented aspirin allergy, or use Plavix concomitantly with aspirin.

- Recent stroke
- Recent MI
- Established peripheral artery disease
- Acute coronary syndrome (unstable angina/ non-Q-wave MI)
- Percutaneous coronary intervention with stent placement

Clients, with the exception of stent placement, are eligible for up to a year of therapy per authorization. Post stent placement clients are eligible for up to 90 days of therapy per authorization.

EDS ProDUR System

The Oklahoma Health Care Authority will now be able to assist pharmacists in providing complete patient care by screening claims through a Prospective Drug Utilization Review process. The following areas will be reviewed through the new ProDUR system:

- Drug – Age Interactions (Pediatric and Geriatric)
- Drug – Drug Interactions
- Drug – Disease Interactions
- Drug – Pregnancy Interactions
- Overuse and Underuse Precautions
- High Dose and Low Dose Alerts
- Therapeutic and Ingredient Duplications

Two types of alerts may occur, either an information-only alert or an action-required alert. For informational alerts, no further action is required of the pharmacist for the claim to be paid. It is expected that the pharmacist will take action if, in their clinical judgment, the situation warrants action on the client level. For action-required alerts, the pharmacist must respond to the alert or make changes to the claim before the claim will be accepted and paid.

The highest level of action-required alerts will be for High Dose and Overuse (or Early Refill). For the High Dose claims, either the quantity/day supply ratio must be corrected or the pharmacy help desk must be contacted and an override requested. Please note that no override for these claims will be granted until the requesting pharmacy has contacted the office of the prescribing physician to verify the dose. The pharmacy must provide the name of the prescriber's office staff who has verified the dose. For Overuse (Early Refill) claims, the current policies will remain in effect and an override will be granted when appropriate. Overrides granted for High Dose and Early Refill do not override the monthly prescription limit.

For all other action-required alerts, an appropriate response can be entered into the DUR response fields to indicate the action taken by the pharmacist. OHCA will monitor the responses and types of alerts being generated and make changes when necessary.

The purpose and goal of providing information through the ProDUR system is to assist pharmacists in providing pharmaceutical care for Medicaid clients. Please remember that only the Early Refill and High Dose alerts require action from the Pharmacy Help Desk. All other action-required alerts will process through the system after the claim is changed and/or the DUR response codes are entered. For questions regarding a ProDUR alert, please contact the pharmacy help desk.

NCPDP version 5.1

The Oklahoma Health Care Authority implemented a new claims processing system in December 2002. Part of the changes associated with the system upgrade is that OHCA Point-of-Sale will accept electronic claims in the NCPDP version 5.1 format only. All versions lower than 5.1 will be rejected.

Although the decision to move the new system to a version 5.1 format was based largely on the requirement of the Health Insurance Portability and Accountability Act (HIPAA), there will be no extensions granted to accept electronic pharmacy claims submitted using the lower versions of the format. Providers who are not able to process electronic claims using version 5.1 will be allowed to process claims electronically over the Internet using the OHCA secure website. Paper claim submissions will also be accepted.

As other third party payers begin to require version 5.1, it will be imperative that pharmacies upgrade their software to comply with HIPAA and with the requirements of each payer. Please contact your software vendor if you have questions about the capability of your system.

Changes in Non-Sedating Antihistamine Prior Authorizations

Changes to this category are the result of an emergency action taken by OHCA to assist in balancing the budget. These criteria are subject to change on or before July 1, 2003.

Clients aged 21 and older are required to provide documentation of a 14 day trial of over the counter (OTC) loratadine in addition to failed trials of traditional antihistamines to receive prior authorization for other non-sedating antihistamines. OTC loratadine is not a covered benefit for these clients.

For clients aged 20 years and younger, OTC loratadine products are covered drugs that do not require PA. A prescription is still required for OTC loratadine. Please dispense and submit claims using the appropriate OTC loratadine NDC

number. Clients under the age of 20 must have a failed documented OTC loratadine trial to receive prior authorization for other non-sedating antihistamines.

The combination products which include a non-sedating antihistamine and a decongestant are no longer covered. Intranasal steroids, Atrovent Nasal Spray, and Astelin remain available without PA.

FDA Approves Low Dose Prempro

The FDA recently approved a new dose of Prempro containing 0.45 mg conjugated estrogens and 1.5 mg medroxyprogesterone. This new dose has shown good tolerability and equal efficacy to Prempro 0.625 mg/2.5 mg tablets based on results of the Women's Health, Osteoporosis, Progestin, and Estrogen (HOPE) Study with 28% less estrogen and 40% less progestin. The new strength is indicated for the treatment of mild to moderate vasomotor symptoms of menopause as well as moderate to severe symptoms of vulvar and vaginal atrophy in postmenopausal women with an intact uterus. At this time, Prempro 0.45 mg/1.5 mg is not approved by the FDA for prevention of postmenopausal osteoporosis. Wyeth, Prempro's manufacturer, expects that the first product shipments will be made in early summer.

In clinical trials, the only adverse events reported more frequently with Prempro 0.45 mg/1.5 mg than placebo were breast pain and irregular bleeding. Health care professionals should be reminded that products in the "Premarin Family" (Premarin, Premarin Vaginal Cream, Prempro, Premphase) should not be used if a woman has undiagnosed and abnormal vaginal bleeding, current or history of breast cancer or an estrogen-dependent neoplasia, current or history of venous thromboembolism (deep vein thrombosis, pulmonary embolism), current or history of arterial thromboembolic disease (stroke, heart attack), liver dysfunction, known or suspected pregnancy, or hypersensitivity to any components of the formulation.

Help Desk Hints

Helpful Hints to get your petitions for medication authorization reviewed and processed more quickly!

- Make sure all information is filled out accurately and thoroughly.
- Make sure the provider number you use on prior authorization petitions is your new **pharmacy** provider number and **NOT** your **DME** provider number.
- Your pharmacy provider number should be exactly 9 digits long plus an alpha character. (If the number you're using does not completely fill the boxes provided, you're using the wrong number.)
- All numbers should completely fill the boxes provided, i.e. Unique Client ID (UCI), NDC and provider prescriber number.
- Writing the numbers and letters clearly and legibly within the boxes provided will help ensure a timely process.
- If your pharmacy uses a typed script to fill our petitions, please use a large font to ensure legibility.
- Any and all separate pages sent with a petition (i.e., copy of prescription, letter from the doctor, additional information), should include the recipient's new 9 digit UCI number so it can be correlated with the correct petition.

- If you have not received a response to your petition within 24 hours, please call to confirm we have received and processed your petition before refaxing. Resubmitting the same petition when it has already been received can confuse issues and further delay processing.
- Take advantage of the boxes at the top of each petition indicating the reason for authorization request. Especially if it is a dosage change or change in pharmacy and an old authorization number needs to be discontinued.
- If you are unsure whether a drug requires prior authorization, please call the pharmacy help desk at 1-800-831-8921 or (405) 271-6349.

Medicaid Pharmacy Help Desk Contact Numbers

Pharmacist (Toll Free)	1-800-831-8921
Pharmacist (OKC Metro)	271-6349
Prescriber (Toll Free)	1-877-269-2728
Prescriber (OKC Metro)	271-9048
Email address:	mcau@ouhsc.edu

OHCA Website
www.ohca.state.ok.us

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