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12-15

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Date prior to or same as filing date

Department of Human Services, Division of Medical Assistance Programs 410
Agency and Division Administrative Rules Chapter Number

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OMAP 41-2006

RULEMAKING ACTION

Rule Filing Caption: January 1, 2007 – prior authorization criteria for Hepatitis C drug therapies; housekeeping -DHS name changes

AMEND: 410-121-0040 and 410-121-0149

Stat. Auth.: ORS 409.010, Department of Human Services function, recipient of federal funds, or Chapter(s), 409.110; Authority of Director
Other Authority: None
Stats. Implemented: ORS 414.065

RULE SUMMARY

The Pharmaceutical Services Program administrative rules govern Division of Medical Assistance Programs' payment for pharmaceutical products and services provided to certain clients. DMAP amended 410-121-0040 to add prior authorization criteria for Hepatitis C drug therapies, based on recommendations and review by the Drug Utilization Review Board (DUR Board) and to take care of necessary housekeeping corrections. DMAP amended 410-121-0149 to take care of necessary housekeeping corrections.

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Jim Edge 12/1/06

Allen Douma, Lynn Read or Jim Edge: Authorized Signers Date

410-121-0040
Prior Authorization Required for Drugs and Products
(1) Prescribing practitioners are responsible for obtaining Prior Authorization (PA) for the drugs and categories of drugs requiring PA in this rule, using the procedures required in OAR 410-121-0060.
(2) All drugs and categories of drugs, including but not limited to those drugs and categories of drugs that require PA as described in this rule, are subject to the following requirements for coverage:
(a) Each drug must be prescribed for conditions funded by OHP in a manner consistent with the Prioritized List of Health Services and its corresponding treatment guidelines, included within the client's benefit package of covered services, and not otherwise excluded or limited.
(b) Each drug must also meet other criteria applicable to the drug or category of drug in these Pharmacy Provider rules, including PA requirements imposed in this rule.
(3) The Department of Human Services (DHS) may require PA for individual drugs and categories of drugs to ensure that the drugs prescribed are indicated for conditions funded by OHP and consistent with the Prioritized List of Health Services and its corresponding treatment guidelines (*see* OAR 410-141-0480). The drugs and categories of drugs for which DHS requires PA for this purpose are listed in Table 410-121-0040-1, with their approval criteria.
(4) DHS may require PA for individual drugs and categories of drugs to ensure medically appropriate use or to address potential client safety risk associated with the particular drug or category of drug, as recommended by the Drug Use Review (DUR) Board and adopted by the Department in this rule (*see* OAR 410-121-0100 for a description of the DUR program). The drugs and categories of drugs for which DHS requires PA for this purpose are included in Table 410-121-0040-2, with their approval criteria.
(5) PA is required for brand name drugs that have two or more generically equivalent products available. Criteria for approval are:
(a) If criteria established in subsection (3) or (4) of this rule applies, follow that criteria.
(b) If (5)(a) does not apply, the prescribing practitioner must document that the use of the generically equivalent drug is medically contraindicated, and provide evidence that either the drug has been used and has failed or that its use is contraindicated based on evidence-based peer reviewed literature that is appropriate to the client's medical condition.
(6) PA will not be required:
(a) When the prescription ingredient cost plus the dispensing fee is less than the PA processing fees as determined by DHS; or,
(b) For over-the-counter (OTC) covered rugs when prescribed for conditions covered under OHP.
(7) Psychotropic prescriptions for children under the age of six cannot be processed when a default 999999 provider number has been entered. If such a default provider number is used, the drug may not be dispensed until PA has been obtained. The PA process will include providing the correct provider number.
Table 121-0040-1
Table 121-004-2
State Auth.: ORS Chap. 409
Stats. Implemented: 414.065

Table 121-0040-1

Drugs Requiring Prior Authorization for Covered Diagnosis

OAR 410-141-0500, and 410-141-0520

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Approval Criteria
Actiq	Fentanyl	Actiq	Any covered diagnosis meeting the recommendations in Table 2 will be approved.
Antifungals, Oral	itraconazole terbinafine	Sporanox Lamisil	Dermatophytosis of the nail and skin and other minor fungal infections are only covered when complicated by an immunocompromised host.
Antifungals, Topical	amphotericin B butenafine ciclopirox clotrimazole clotrimazole/betamethasone econazole ketoconazole naftifine nystatin/triamcinolone oxiconazole sertaconazole sulconazole terbinafine tolnaftate undecylenic acid various others	Fungizole Lotrimin Ultra;Mentax Loprox; Penlac Lotrimin; Mycelex Lotrisone Spectazole Nizoral Naftin Mycolog II Oxistat Ertaczo Exelderm Lamisil Tinactin Desenex Various others	Dermatophytosis of the nail and skin and other minor fungal infections are only covered when complicated by an immunocompromised host.

Antihistamines, Selected	acrivas/pseudoephedrine certrizine certrizine/pseudoephedrine desloratadine fexofendadine fexofendadine/pseudoephrine loratadine loratidine/pseudoephedrine	Semprex-D Zyrtec Zyrtec-D Clarinex Allegra Allegra-D Claritin Claritin-D	Allergic rhinitis is not a covered diagnosis unless it is complicated with other diagnoses (e.g. periorbital inflammation or other ocular complications; chronic sinusitis with 3 more episodes during past 12 months; sinus surgery, or frequent sinus procedures). Use must meet recommendations in Table 2.
Antiviral, Topical	Acyclovir docosanol peniciclovir	Zovirax Abreva Denavir	HSV infections are covered when complicated by an immunocompromised host.
Benign Prostatic Hypertrothphy Drugs	alfuzosin dutasteride finasteride tamsulosin	Uroxatral Avodart Proscar Flomax	Treatment of enlarged prostate is not covered unless complicated by obstruction. The cosmetic use of these drugs for baldness is not covered.
Brand Drugs, Multi-Source	Various	Various	A covered diagnosis is required for use of a brand product when a generic is available.
Carisoprodol drugs	carisoprodol and all combination products	Soma, Soma Compound, various others	Any above the line diagnosis will be approved within dosing recommendations in Table 2.

Dronabinol	dronabinol	Marinol	Any covered diagnosis meeting the recommendations in Table 2 will be approved.
Gabapentin	gabapentin	Neurontin	Any covered diagnosis meeting the recommendations in Table 2 will be approved.
Growth Hormones	somatrem somatropin	Protropin Genotropin Humatrope Norditropin Nurotropin Nurotropin AQ Nurotropin Depot Saizen Serostim	Any covered diagnosis meeting recommendations in Table 2 will be approved.
Ketoralac	ketoralac	Toradol	Any covered diagnosis will be approved within the dosing recommendations in Table 2.
Laxative, selected	polyethylene glycol	Miralax	Any covered diagnosis will be approved.
Leukotriene receptor antagonists	montelukast	Singular	Allergic rhinitis is not a covered diagnosis unless it is complicated with other diagnoses (e.g. periorbital inflammation or other ocular complications; chronic sinusitis with 3 more episodes during past 12 months; sinus surgery, or frequent sinus procedures). Asthma is a covered diagnosis.

Nasal Inhalers	azelastine cromolyn beclomethasone budesonide flunisolide fluticasone mometasone triamcinolone	Astelin Nasalcrom RA Beconase Rhinocort Nasalide Flonase Nasonex Nasacort	Allergic rhinitis is not a covered diagnosis unless it is complicated with other diagnoses (e.g. periorbital inflammation or other ocular complications; chronic sinusitis with 3 more episodes during past 12 months; sinus surgery, or frequent sinus procedures).
Nutritional Support, Enteral or oral	Nutritional bars, liquids, packets, powders, & wafers, and various others	Ensure, Ensure Plus, Nephro, Pediasure, Promod and various others	Diagnosis being treated must be a covered diagnosis and fall within the recommendations in Table 2.
Opioid Drugs, combination products (aka narcotics)	codeine/acetaminophen hydrocodone/acetaminophen dihydrocodone/acetaminophen/ caffeine oxycodone/acetaminophen propoxyphene/acetaminophen pentazocine/acetaminophen codeine/aspirin codeine/aspirin/caffeine oxycodone/aspirin pentazocine/aspirin propoxyphene/aspirin/caffeine various others	Tylenol with Codeine Vicodin, Lortab DHC Plus Percocet Darvocet-N-100 Talacen Empirin with Codeine Fiorinal with Codeine Percodan Talwin Compound Darvon Compound Various others	Any covered pain diagnosis that is appropriate will be approved within dose recommendations in Table 2.
Oxycodone Extended Action	Oxycodone	OxyContin	Doses above 120mg/day require a prior authorization to insure the diagnosis is covered.

Psoriasis Drugs	alefacept efalizumab methoxsalen trioxsalen isotretinoin acitretin antralin tazarotene calcipotriene coal tar	Amevive Raptiva Psoralen, 8-MOP Trisoralen Accutane, Sotret Soriatane Psoriatec, Drithocreme Tazorac Dovonex Various	Only Stage III, IV psoriasis and psoriatic arthritis are covered. Stages I and II are not. Other, non-experimental, covered diagnoses will be approved.
Sedatives	~~chloral hydrate~~ estazolam eszopiclone flurazepaam quazepam ramelteon temazepam triazolam zaleplon zolpidem	~~Aquachlor, Noctec~~ Prosom Lunesta Dalmane Doral Rozerem Restoril Halcion Sonta Ambien	Chronic insomnia is ~~Sleep disorders~~ not ~~related to sleep apnea are not~~ a covered diagnoses. ~~Only~~ Sleep disorders contributing to covered diagnoses (e.g. sleep apnea, bipolar affective disorder, depression, etc.) ~~diagnoses that are covered~~ will be approved. ~~within the dosing recommendations in Table 2.~~
Stimulants	dextroamphetamine methamphetamine mixed amphetamines dexmethylphenidate methylphenidate	Dexedrine, Dextristat Desoxyn Adderall, Adderall XR Focalin Methylin, Metadate, Ritalin	Obesity is not a covered diagnoses. Use for ADHD, Narcolepsy and other covered diagnoses will be approved within the doses recommended in Table 2.
Testosterone, Topical	testosterone	Testoderm Androgel Androgem DHEA	Will be approved for covered diagnoses (e.g. Primary hypogonadism, Hypogonadotropic hypogonadism, AIDS related cachexia)

Weight Loss Drugs	orlistat sibutramine phentermine	Xenical Meridia Fastin	Obesity treatment is not a covered diagnosis. Only diagnoses that are covered will be approved.

Table 121-0040-2

Drugs Requiring Prior Authorization for Medically Appropriate Use

OAR 410-141-0500, and 410-141-0520

Drug Class	Drug Generic (list is subject to market fluctuations)	Drug Brand (list is subject to market fluctuations)	Use Criteria
Actiq	Fentanyl	Actiq	Use restricted to that described in the FDA labeling
Anti-emetics, selected	dolasteron granisetron ondansetron aprepitant	Anzemet Kytril Zofran Emend	Chronic use (>3 days/week) is restricted to indications that are supported by the medical evidence (e.g. nausea associated with chemotherapy)
Antihistamines, Selected	acrivas/pseudoephedrine certrizine certrizine/pseudoephedrine desloratadine fexofendadine fexofendadine/pseudoephrine loratadine loratidine/pseudoephedrine	Semprex-D Zyrtec Zyrtec-D Clarinex Allegra Allegra-D Claritin Claritin-D	Use is restricted to covered diagnoses and therapy is recommended to include an asthma controller drug. Duplication with similar products (i.e. nasal inhalers) is not recommended.
Becaplermin	Becaplermin	Regranex	Use restricted to diabetic neuropathic ulcers.
Carisoprodol drugs	carisoprodol and all combination products	Soma, Soma Compound, various others	Carisoprodol is restricted to short-term use (56 tablets / 90days)

Dronabinol	dronabinol	Marinol	Dronabinol use is restricted to indications where the medical evidence supports its use (e.g. nausea associated with chemotherapy or cachexia)
Gabapentin	gabapentin	Neurontin	Gabapentin use is restricted to indications where the medical evidence supports its use (e.g. diabetic neuropathy, epilepsy, post-herpetic neuralgia).
Growth Hormones	somatrem somatropin	Protropin Genotropin Humatrope Norditropin Nurotropin Nurotropin AQ Nurotropin Depot Saizen Serostim	Growth hormone use is restricted to indications of documented hormone deficiency. Serostim may be approved for AIDS wasting within approved parameters.
Hepatitis C Drugs	Pegylated Interferon Ribavirin/Interferon A-2B Ribavirin	Peg-Intron Pegasys Rebetron Rebetol	Restricted to patient selection criteria based on the Statewide Viral Hepatitis Planning Group, NIH and CDC recommendations.
Ketoralac	ketoralac	Toradol	Ketoralac is restricted to short-term use (5 days every 60 days)
Leukotriene receptor antagonists	montelukast	Singular	Duplication with similar products (i.e. nasal inhalers, antihistamines) is not recommended. It

			is not indicated for COPD and other respiratory disorders without an asthma component.
Migraine Drugs (aka Triptans)	almotriptan eletriptan frovatriptan naratriptan rizatriptan sumatriptan zolmitriptan	Axert Relpax Frova Amerge Maxalt, Maxalt MLT Imitrex Zomig, Zomig ZMT	Monthly quantity limits are enforced per the FDA maximum dose labeling.
Nasal Inhalers	azelastine cromolyn beclomethasone budesonide flunisolide fluticasone mometasone triamcinolone	Astelin Nasalcrom RA Beconase Rhinocort Nasalide Flonase Nasonex Nasacort	Use is restricted to covered diagnoses and therapy is also recommended to include an asthma controller drug. Duplication with similar products (i.e. antihistamines) is not recommended.
Nutritional Support, Enteral or oral	Nutritional bars, liquids, packets, powders, & wafers, and various others	Ensure, Ensure Plus, Nephro, Pediasure, Promod and various others	These products are restricted to patients unable to take food orally in sufficient quantity to maintain adequate weight. Requires annual nutritional assessment to assess continued need.
Opioid Drugs, combination products (aka narcotics)	codeine/acetaminophen hydrocodone/acetaminophen dihydrocodone/acetaminophen/caffeine oxycodone/acetaminophen propoxyphene/acetaminophen pentazocine/acetaminophen	Tylenol with Codeine Vicodin, Lortab DHC Plus Percocet Darvocet-N-100 Talacen Empirin with Codeine Fiorinal with Codeine	Monthly quantity limits are enforced per the FDA maximum dose labeling for acetaminophen or aspirin.

	codeine/aspirin codeine/aspirin/caffeine oxycodone/aspirin pentazocine/aspirin propoxyphene/aspirin/caffeine various others	Percocet Talwin Compound Darvon Compound Various others	
Polypharmacy	Various	Various	See: 410-121-0033
Proton Pump Inhibitors	esomeprazole lansoprazole lansoprazole w/naproxen omeprazole pantoprazole rabeprazole	Nexium Prevacid NapraPAC Prilosec Protonix Aciphex	PPI therapy beyond 8 weeks requires prior authorization. Chronic use is restricted to those who have failed H2-antagonist therapy or those with severe disease (e.g. Barrett's, ZE, etc.)
Sedatives	~~chloral hydrate~~ estazolam flurazepam quazepam temazepam triazolam ~~zaleplon~~ ~~zolpidem~~	~~Aquachlor, Noctec~~ Prosom Dalmane Doral Restoril Halcion ~~Sonta~~ ~~Ambien~~	Quantities are restricted to 15 doses/30days unless a covered diagnosis is provided.
Stimulants	dextroamphetamine methamphetamine mixed amphetamines dexmethylphenidate methylphenidate	Dexedrine, Dextristat Desoxyn Adderall, Adderall XR Focalin Methylin, Metadate, Ritalin	Doses greater than the FDA labeling or above the weight-based doses recommended in the Pediatric Dosing Handbook require prior authorization.

410-121-0149
Medicaid Temporary Prescription Drug Assistance for Fully Dual Eligible Medicare Part D Clients
(1) This rule is a temporary solution implemented because many pharmacies are not able to verify that the fully dual eligible client is enrolled in one of the federal Medicare Prescription Drug Plans or that the client is eligible for low-income subsidy assistance. DMAP will continue to work with the federal Medicare program to resolve these implementation issues with Part D coverage.
(2) Effective January 14, 2006, for the purposes described in Subsection (1), enrolled pharmacies may send the Division of Medical Assistance Programs (DMAP) claims for Part D drugs and cost-sharing obligations of clients who have both Medicare and Medicaid coverage (fully dual eligible clients) if:
(a) The drug(s) was covered by DMAP for fully dual eligible clients prior to January 1, 2006; and
(b) The pharmacy has attempted to bill Medicare's Part D system but cannot resolve the claim by:
(A) Continuing to bill the Medicare Part D plan as the primary payer identified through an E-1 query;
(B) Trying to resolve the issue with the Medicare Part D plan directly;
(C) Billing Wellpoint/Anthem, Medicare's Point of Sale Solution.
(3) If all the criteria in Subsection (2) are met, then DMAP will consider paying the claim or a portion of the claim, as follows:
(a) The pharmacy must contact the DHS Medicare hotline at 1-877-585-0007 to obtain authorization for claim submission;
(b) The fully dual eligible client is responsible for paying the appropriate Medicare copayment;
(c) DMAP payment authorization will be limited to not greater than a one-month supply; and
(d) DMAP's reimbursement amount will be limited to the amount the Part D drug plan would have paid, had the Part D drug plan adjudicated the claim first, or the amount DMAP would pay for Medicaid clients who are not also Medicare beneficiaries.
(4) This rule supersedes all other rules relating to the limitations and exclusions of drug coverage for clients with Medicare Part D.
Stat. Auth. ORS 409.010, ORS 409.050, and 2005 OR law, Ch. 754 (SB 1088)
Statutes Implemented: ORS 414.065