

Secretary of State  
Certificate and Order for Filing  
**TEMPORARY ADMINISTRATIVE RULES**  
A Statement of Need and Justification accompanies this form..

I certify that the attached copies\* are true, full and correct copies of the TEMPORARY Rule(s) adopted on [upon filing] by the  
Date prior to or same as filing date

Oregon Health Authority, Division of Medical Assistance Programs 410  
Agency and Division Administrative Rules Chapter Number

Cheryl Peters, 500 Summer St Ne, Salem, OR 97301 503-945-6527  
Rules Coordinator Address Telephone

to become effective [ 7/23/12 ] through [ 1/18/2013 ].  
Date upon filing or later A maximum of 180 days including the effective date.

**RULE CAPTION**

Amending Preferred Drug List and Prior Authorization Guide – April 26, 2012 DUR/P&T Action

**Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.**

**RULEMAKING ACTION**

List each rule number separately, 000-000-0000.

Secure approval of new rule numbers (Adopted rules) with the Administrative Rules Unit prior to filing

**ADOPT:**

**AMEND:** 410-121-0030 and 410-121-0040

**SUSPEND:**

Stat. Auth.: ORS 413.032, 413.042, 414.065, 414.325, and 414.330 to 414.414

Other Auth.: None.

Stats. Implemented: ORS 414.065; 414.325, 414.334, 414.361, 414.369 and 414.371

**RULE SUMMARY**

The Pharmaceutical Services Program administrative rules (Division 121) govern Division payments for services provided to certain clients. The Division needs to amend rules as follows:

410-121-0030:

- Add Gastrointestinal Clostridium Difficile class to the PDL. Add metronidazole and vancomycin as preferred products.
- Add Pulmonary Smoking Cessation class to the PDL. Add bupropion sustained release, nicotine patch, nicotine polacrilex gum, nicotine polacrilex lozenge and varenicline tartrate as preferred products.
- Remove Baraclude® (entecavir) from the Antiviral Hepatitis B class

410-121-0040:

- Kalydeco® (ivacaftor) – new criteria
- Egrifta® (tesamorelin) – new criteria
- Amylin Analogs – update criteria
- Incretin Enhancers – update criteria
- Incretin Mimetics – update criteria
- Dificid® (fidaxomicin) – new criteria
- Smoking Cessation – new criteria
- Hepatitis B – new criteria

Authorized Signer

Printed name

Date

\*With this original and Statement of Need, file one photocopy of certificate, one paper copy of rules listed in Rulemaking Actions, and electronic copy of rules. ARC 940-2005

Secretary of State

**STATEMENT OF NEED AND JUSTIFICATION**

A Certificate and Order for Filing Temporary Administrative Rules accompanies this form.

Oregon Health Authority, Division of Medical Assistance Programs

410

Agency and Division

Administrative Rules Chapter Number

In the Matter of: OAR 410-121-0030 and 410-121-0040

Rule Caption: Amending Preferred Drug List and Prior Authorization Guide – April 26, 2012 DUR/P&amp;T Action

Statutory Authority: ORS 413.032, 413.042, 414.065, 414.325, and 414.330 to 414.414

Other Authority: None.

Stats. Implemented: ORS 414.065; 414.325, 414.334, 414.361, 414.369 and 414.371

Need for the Temporary Rule(s): The Pharmaceutical Services Program administrative rules (division 121) govern Division payments for services provided to certain clients. The Division permanently amended 410-121-0030 and 410-121-0040 per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made in the April 26, 2012 meeting.

The Authority needs to implement changes to the Preferred Drug List and Prior Authorization Guide to ensure the safe and appropriate use of cost effective prescription drugs for the Oregon Health Plan's fee-for-service recipients.

410-121-0030:

- Add Gastrointestinal Clostridium Difficile class to the PDL. Add metronidazole and vancomycin as preferred products.
- Add Pulmonary Smoking Cessation class to the PDL. Add bupropion sustained release, nicotine patch, nicotine polacrilex gum, nicotine polacrilex lozenge and varenicline tartrate as preferred products.
- Remove Baraclude® (entecavir) from the Antiviral Hepatitis B class

410-121-0040:

- Kalydeco® (ivacaftor) – new criteria
- Egrifta® (tesamorelin) – new criteria
- Amylin Analogs – update criteria
- Incretin Enhancers – update criteria
- Incretin Mimetics – update criteria
- Difucid® (fidaxomicin) – new criteria
- Smoking Cessation – new criteria
- Hepatitis B – new criteria

Documents Relied Upon, and where they are available: Or Law 2011, chapter 720 (HB 2100):

<http://www.leg.state.or.us/11reg/measpdf/hb2100.dir/hb2100.en.pdf>

Justification of Temporary Rule(s): The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority and clients enrolled in Oregon's Medicaid Program by delaying the reassessment and update of preferred drug lists and prior authorization requirements. These rules need to be adopted promptly so the Authority can ensure the safe and appropriate use of Medicaid covered drugs.

Authorized Signer

Printed name

Date

## **410-121-0030 Practitioner-Managed Prescription Drug Plan**

(1) The Practitioner-Managed Prescription Drug Plan (PMPDP) is a plan that ensures that fee-for-service clients of the Oregon Health Plan shall have access to the most effective prescription drugs appropriate for their clinical conditions at the best possible price:

(a) Licensed health care practitioners (informed by the latest peer reviewed research), make decisions concerning the clinical effectiveness of the prescription drugs;

(b) The licensed health care practitioners also consider the health condition of a client or characteristics of a client, including the client's gender, race or ethnicity.

(2) PMPDP Preferred Drug List (PDL):

(a) The PDL is the primary tool that the Division developed to inform licensed health care practitioners about the results of the latest peer-reviewed research and cost effectiveness of prescription drugs;

(b) The PDL (as defined in 410-121-0000 (cc) consists of prescription drugs that the Division, in consultation with the Drug Use Review (DUR) / Pharmacy & Therapeutics Committee (P&T), has determined represent the most effective drug(s) available at the best possible price;

(c) The PDL shall include drugs that are Medicaid reimbursable and the Food and Drug Administration (FDA) has determined to be safe and effective.

(3) PMPDP PDL Selection Process:

(a) The Division shall utilize the recommendations made by the P&T, that result from an evidence-based evaluation process, as the basis for selecting the most effective drug(s);

(b) The Division shall determine the drugs selected in (3)(a) that are available for the best possible price and shall consider any input from the P&T about other FDA-approved drug(s) in the same class that are available for a lesser relative price. The Division shall determine relative price using the methodology described in subsection (4);

(c) The Division shall evaluate selected drug(s) for the drug classes periodically:

(A) Evaluation shall occur more frequently at the discretion of the Division if new safety information or the release of new drugs in a class or other information which makes an evaluation advisable;

(B) New drugs in classes already evaluated for the PDL shall be non-preferred until the new drug has been reviewed by the P&T;

(C) The Division shall make all changes or revisions to the PDL, using the rulemaking process and shall publish the changes on the Division's Pharmaceutical Services provider rules Web page.

(4) Relative cost and best possible price determination:

(a) The Division shall determine the relative cost of all drugs in each selected class that are Medicaid reimbursable and that the FDA has determined to be safe and effective;

(b) The Division may also consider dosing issues, patterns of use and compliance issues. The Division shall weigh these factors with any advice provided by the P&T in reaching a final decision;

(5) Pharmacy providers shall dispense prescriptions in the generic form, unless:

(a) The practitioner requests otherwise, subject to the regulations outlined in OAR 410-121-0155;

(b) The brand name medication is listed as preferred on the PDL.

(6) The exception process for obtaining non-preferred physical health drugs that are not on the PDL drugs shall be as follows:

(a) If the prescribing practitioner, in their professional judgment, wishes to prescribe a physical health drug not on the PDL, they may request an exception, subject to the requirements of OAR 410-121-0040;

(b) The prescribing practitioner must request an exception for physical health drugs not listed in the PDL subject to the requirements of OAR 410-121-0060;

(c) Exceptions shall be granted in instances:

(A) Where the prescriber in their professional judgment determines the non-preferred drug is medically appropriate after consulting with the Division or the Oregon Pharmacy Help Desk; or

(B) Where the prescriber requests an exception subject to the requirement of (6)(b) and fails to receive a report of PA status within 24 hours, subject to OAR 410-121-0060.

(7) Table 121-0030-1, PMPDP PDL

[ED. NOTE: Tables referenced are not included in rule text. [Click here for PDF copy of table\(s\).](#)]

Stat. Auth.: ORS 409.025, 409.040, 409.110, 414.065, 413.042 and 414.325

Stats. Implemented: ORS 414.065

7-23-12 (T)

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred
Allergy/Cold	Antihistamines - 2nd Generation	CETIRIZINE HCL SOLUTION
		CETIRIZINE HCL TABLET
		LORATADINE SOLUTION
		LORATADINE TAB RAPDIS ***
		LORATADINE TABLET
Analgesics	Gout	ALLOPURINOL TABLET
		COLCHICINE/PROBENECID TABLET
Analgesics	Long-Acting Opioids	FENTANYL * PATCH TD72
		METHADONE HCL (METHADONE INTENSOL®) * ORAL CONC
		METHADONE HCL * SOLUTION
		METHADONE HCL * TABLET
		MORPHINE SULFATE * TABLET ER
Analgesics	NSAIDs	DICLOFENAC POTASSIUM TABLET
		DICLOFENAC SODIUM TABLET DR
		ETODOLAC TABLET
		FLURBIPROFEN TABLET
		IBUPROFEN CAPSULE
		IBUPROFEN DROPS SUSP
		IBUPROFEN ORAL SUSP
		IBUPROFEN TAB CHEW
		IBUPROFEN TABLET
		INDOMETHACIN CAPSULE
		KETOPROFEN CAPSULE
		KETOROLAC TROMETHAMINE * TABLET
		MELOXICAM TABLET
		NABUMETONE TABLET
		NAPROXEN TABLET
		NAPROXEN TABLET DR
		NAPROXEN SODIUM TABLET
		OXAPROZIN TABLET
		SALSALATE TABLET
SULINDAC TABLET		

\* Drug coverage subject to meeting clinical prior authorization criteria.

\*\* Drug coverage subject to quantity limits.

\*\*\*Certain strengths may require Prior Authorization

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred	
Analgesics	Short-Acting Opioids	CODEINE SULFATE *	TABLET
		HYDROCODONE BIT/ACETAMINOPHEN **	TABLET ***
		HYDROMORPHONE HCL *	TABLET
		MORPHINE SULFATE *	SOLUTION
		MORPHINE SULFATE *	TABLET
		OXYCODONE HCL *	SOLUTION
		OXYCODONE HCL *	TABLET
		OXYCODONE HCL/ACETAMINOPHEN **	CAPSULE
		OXYCODONE HCL/ACETAMINOPHEN **	TABLET ***
		TRAMADOL HCL	TABLET
Analgesics	Skeletal Muscle Relaxants	BACLOFEN	TABLET
		CYCLOBENZAPRINE HCL	TABLET ***
		TIZANIDINE HCL	TABLET
Analgesics	Topical	CAPSAICIN	CREAM (G) ***
Analgesics	Tryptans, Injection	IMITREX® - BRAND ONLY **	CARTRIDGE
		IMITREX® - BRAND ONLY **	PEN INJCTR
		IMITREX® - BRAND ONLY **	VIAL
Analgesics	Tryptans, Nasal	IMITREX® - BRAND ONLY **	SPRAY
		ZOLMITRIPTAN (ZOMIG®) **	SPRAY
Analgesics	Tryptans, Oral	NARATRIPTAN HCL **	TABLET
		SUMATRIPTAN SUCCINATE **	TABLET
Antibiotics	Amoxicillin-Clavulanate	AMOXICILLIN/POTASSIUM CLAV	SUSP RECON
		AMOXICILLIN/POTASSIUM CLAV	TAB CHEW
		AMOXICILLIN/POTASSIUM CLAV	TABLET
Antibiotics	Cephalosporin, 1st Gen	CEPHALEXIN	CAPSULE ***
		CEPHALEXIN	SUSP RECON ***
Antibiotics	Cephalosporin, 2nd Gen	CEFPROZIL	SUSP RECON
		CEFPROZIL	TABLET
		CEFUROXIME AXETIL	TABLET
Antibiotics	Cephalosporin, 3rd Gen	CEFDINIR	CAPSULE
		CEFDINIR	SUSP RECON
		CEFPODOXIME PROXETIL	TABLET

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Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred	
Antibiotics	Fluoroquinolones, Oral	CIPROFLOXACIN (CIPRO®)	SUS MC REC
		CIPROFLOXACIN HCL	TABLET
		LEVOFLOXACIN	SOLUTION
		LEVOFLOXACIN	TABLET
		NORFLOXACIN	TABLET
Antibiotics	Macrolide / Ketolide	AZITHROMYCIN	SUSP RECON
		AZITHROMYCIN	TABLET
		CLARITHROMYCIN	TABLET
		ERYTHROMYCIN BASE	CAPSULE DR
		ERYTHROMYCIN BASE (ERY-TAB®)	TABLET DR
		ERYTHROMYCIN ETHYLSUCCINATE	ORAL SUSP
		ERYTHROMYCIN ETHYLSUCCINATE	TABLET
		ERYTHROMYCIN ETHYLSUCCINATE (E.E.S. 200®)	ORAL SUSP
		ERYTHROMYCIN ETHYLSUCCINATE (E.E.S. 400®)	TABLET
		ERYTHROMYCIN ETHYLSUCCINATE (ERYPED 200®)	SUSP RECON
		ERYTHROMYCIN ETHYLSUCCINATE (ERYPED 400®)	SUSP RECON
		ERYTHROMYCIN STEARATE	TABLET
		Antibiotics	Tetracyclines, Oral
DOXYCYCLINE HYCLATE	TABLET		
DOXYCYCLINE MONOHYDRATE	CAPSULE ***		
DOXYCYCLINE MONOHYDRATE (VIBRAMYCIN®)	SUSP RECON		
TETRACYCLINE HCL	CAPSULE		
Antifungal	Antifungal, Oral	CLOTRIMAZOLE	TROCHE
		FLUCONAZOLE	SUSP RECON
		FLUCONAZOLE	TABLET
		KETOCONAZOLE	TABLET
		NYSTATIN	ORAL SUSP
		NYSTATIN	TABLET
Antiviral	Hepatitis B	LAMIVUDINE (EPIVIR HBV®) *	SOLUTION
		LAMIVUDINE (EPIVIR HBV®) *	TABLET
		TENOFOVIR DISOPROXIL FUMARATE (VIREAD®) *	TABLET

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Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred	
Antiviral	Hepatitis C	BOCEPREVIR (VICTRELIS®) *	CAPSULE
		PEGINTERFERON ALFA-2A (PEGASYS®) *	KIT
		PEGINTERFERON ALFA-2B (PEGINTRON REDIPEN®) *	PEN IJ KIT
		PEGINTERFERON ALFA-2B (PEGINTRON®) *	KIT ***
		RIBAVIRIN *	CAPSULE
		RIBAVIRIN *	TABLET
		TELAPREVIR (INCIVEK®) *	TABLET
Antiviral	HSV, Oral	ACYCLOVIR	CAPSULE
		ACYCLOVIR	ORAL SUSP
		ACYCLOVIR	TABLET
Antiviral	Influenza	AMANTADINE HCL	CAPSULE
		AMANTADINE HCL	SYRUP
		AMANTADINE HCL	TABLET
		OSELTAMIVIR PHOSPHATE (TAMIFLU®) **	CAPSULE
		OSELTAMIVIR PHOSPHATE (TAMIFLU®) **	SUSP RECON
		RIMANTADINE HCL	TABLET
Cardiovascular	Anticoagulants, Oral	WARFARIN SODIUM	TABLET
Cardiovascular	Anticoagulants, Subcutaneous	DALTEPARIN SODIUM,PORCINE (FRAGMIN®)	DISP SYRIN
		LOVENOX® - BRAND ONLY	DISP SYRIN
Cardiovascular	Beta-Blockers	ACEBUTOLOL HCL	CAPSULE
		ATENOLOL	TABLET
		CARVEDILOL	TABLET
		LABETALOL HCL	TABLET
		METOPROLOL TARTRATE	TABLET
		NADOLOL	TABLET
		PROPRANOLOL HCL	TABLET
Cardiovascular	Calcium Channel Blockers - DH	AMLODIPINE BESYLATE	TABLET
		NICARDIPINE HCL	CAPSULE
		NIFEDIPINE	TAB ER 24
		NIFEDIPINE	TABLET ER

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Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred	
Cardiovascular	Calcium Channel Blockers - NDH	DILTIAZEM HCL	CAP ER 12H
		DILTIAZEM HCL	CAP ER 24H
		DILTIAZEM HCL	CAP ER DEG
		DILTIAZEM HCL	CAPSULE ER
		DILTIAZEM HCL	TABLET
		VERAPAMIL HCL	CAP24H PEL
		VERAPAMIL HCL	TABLET
		VERAPAMIL HCL	TABLET ER
Cardiovascular	DRIs, ACE-Is and ARBs	BENAZEPRIL HCL	TABLET
		CAPTOPRIL	TABLET
		ENALAPRIL MALEATE	TABLET
		FOSINOPRIL SODIUM	TABLET
		LISINOPRIL	TABLET
		LOSARTAN POTASSIUM	TABLET
		MOEXIPRIL HCL	TABLET
		OLMESARTAN MEDOXOMIL (BENICAR®)	TABLET
		QUINAPRIL HCL	TABLET
		RAMIPRIL	CAPSULE
		RAMIPRIL	TABLET
		TELMISARTAN (MICARDIS®)	TABLET
Cardiovascular	DRIs, ACE-Is and ARBs + HCT	BENAZEPRIL/HYDROCHLOROTHIAZIDE	TABLET
		CAPTOPRIL/HYDROCHLOROTHIAZIDE	TABLET
		ENALAPRIL/HYDROCHLOROTHIAZIDE	TABLET
		FOSINOPRIL/HYDROCHLOROTHIAZIDE	TABLET
		LISINOPRIL/HYDROCHLOROTHIAZIDE	TABLET
		LOSARTAN/HYDROCHLOROTHIAZIDE	TABLET
		MOEXIPRIL/HYDROCHLOROTHIAZIDE	TABLET
		OLMESARTAN/HYDROCHLOROTHIAZIDE (BENICAR HCT®)	TABLET
		QUINAPRIL/HYDROCHLOROTHIAZIDE	TABLET
		TELMISARTAN/HYDROCHLOROTHIAZID (MICARDIS HCT®)	TABLET
Cardiovascular	HP Statins & Combos	LIPITOR® - BRAND ONLY	TABLET
		SIMVASTATIN	TABLET
Cardiovascular	LMP Statins & Combos	LOVASTATIN	TABLET
		PRAVASTATIN SODIUM	TABLET

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**Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012**

<b>System</b>	<b>Class</b>	<b>Preferred</b>
Cardiovascular	Platelet Inhibitors	ASPIRIN TABLET
		ASPIRIN/DIPYRIDAMOLE (AGGRENOX®) CPMP 12HR
		CLOPIDOGREL BISULFATE (PLAVIX®) TABLET
		DIPYRIDAMOLE TABLET
Dermatologic	Antifungal, Topical	MICONAZOLE NITRATE CREAM (G)
		NYSTATIN CREAM (G)
		NYSTATIN OINT. (G)
Dermatologic	Anti-Parasite	PERMETHRIN CREAM (G)
		PERMETHRIN LIQUID
		PIP BUTOX/PYRETHRINS/PERMETH KIT
		PIPERONYL BUTOXIDE/PYRETHRINS GEL (GRAM)
		PIPERONYL BUTOXIDE/PYRETHRINS KIT
		PIPERONYL BUTOXIDE/PYRETHRINS LIQUID
		PIPERONYL BUTOXIDE/PYRETHRINS SHAMPOO
Dermatologic	Impetigo Agents	BACITRACIN OINT. (G)
		BACITRACIN ZINC OINT. (G)
		BACITRACIN/POLYMYXIN B SULFATE OINT. (G)
		GENTAMICIN SULFATE CREAM (G)
		MUPIROCIN OINT. (G)
		NEOMY SULF/BACITRAC ZN/POLY OINT. (G)
Dermatologic	Psoriasis, Topical	CALCIPOTRIENE (DOVONEX®) * CREAM (G)
		CALCIPOTRIENE * SOLUTION
		CALCIPOTRIENE/BETAMETHASONE (TACLONEX®) * OINT. (G)
		TAZAROTENE (TAZORAC®) * CREAM (G)
		TAZAROTENE (TAZORAC®) * GEL (GRAM)

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Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred	
Dermatologic	Steroids, Topical	ALCLOMETASONE DIPROPIONATE	CREAM (G)
		ALCLOMETASONE DIPROPIONATE	OINT. (G)
		BETAMETHASONE DIPROPIONATE	CREAM (G)
		BETAMETHASONE DIPROPIONATE	LOTION
		BETAMETHASONE DIPROPIONATE	OINT. (G)
		BETAMETHASONE VALERATE	CREAM (G)
		BETAMETHASONE VALERATE	OINT. (G)
		CLOBETASOL PROPIONATE	CREAM (G)
		CLOBETASOL PROPIONATE	OINT. (G)
		DESONIDE	CREAM (G)
		DESONIDE	OINT. (G)
		FLUOCINOLONE ACETONIDE	CREAM (G)
		FLUOCINOLONE ACETONIDE	SOLUTION
		FLUOCINONIDE	CREAM (G)
		FLUOCINONIDE	SOLUTION
		FLUOCINONIDE/EMOLLIENT	CREAM (G)
		HYDROCORTISONE	CREAM (G)
		HYDROCORTISONE	OINT. (G)
		HYDROCORTISONE ACETATE	CREAM (G)
		HYDROCORTISONE BUTYRATE	SOLUTION
TRIAMCINOLONE ACETONIDE	CREAM (G)		
TRIAMCINOLONE ACETONIDE	OINT. (G)		
Endocrine	Androgens	TESTOSTERONE (ANDRODERM®) *	PATCH TD24
		TESTOSTERONE (TESTIM®) *	GEL (GRAM)
		TESTOSTERONE CYPIONATE	VIAL
		TESTOSTERONE ENANTHATE	VIAL
Endocrine	Bone Metabolism Drugs	ALENDRONATE SODIUM	TABLET
		ALENDRONATE SODIUM/VITAMIN D3 (FOSAMAX PLUS D®)	TABLET
		IBANDRONATE SODIUM (BONIVA®)	TABLET
Endocrine	DM-Amylin Analogs	PRAMLINTIDE ACETATE (SYMLINPEN 120®) *	PEN INJCTR
		PRAMLINTIDE ACETATE (SYMLINPEN 60®) *	PEN INJCTR

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Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred	
Endocrine	DM-Insulin	HUM INSULIN NPH/REG INSULIN HM (HUMULIN 50-50®)	VIAL
		HUM INSULIN NPH/REG INSULIN HM (HUMULIN 70-30®)	VIAL
		HUM INSULIN NPH/REG INSULIN HM (HUMULIN 70-30®) *	INSULN PEN
		HUM INSULIN NPH/REG INSULIN HM (NOVOLIN 70/30®)	VIAL
		HUM INSULIN NPH/REG INSULIN HM (NOVOLIN 70-30 INNOLET®) *	INSULN PEN
		INSULIN ASPART (NOVOLOG®)	VIAL
		INSULIN ASPART (NOVOLOG®) *	CARTRIDGE
		INSULIN ASPART (NOVOLOG®) *	INSULN PEN
		INSULIN GLARGINE,HUM.REC.ANLOG (LANTUS SOLOSTAR®) *	INSULN PEN
		INSULIN GLARGINE,HUM.REC.ANLOG (LANTUS®)	VIAL
		INSULIN GLARGINE,HUM.REC.ANLOG (LANTUS®) *	CARTRIDGE
		INSULIN LISPRO (HUMALOG®)	VIAL
		INSULIN LISPRO (HUMALOG®) *	CARTRIDGE
		INSULIN LISPRO (HUMALOG®) *	INSULN PEN
		INSULIN NPL/INSULIN LISPRO (HUMALOG MIX 50/50®) *	INSULN PEN
		INSULIN NPL/INSULIN LISPRO (HUMALOG MIX 50-50®)	VIAL
		INSULIN NPL/INSULIN LISPRO (HUMALOG MIX 75-25®)	VIAL
		INSULIN NPL/INSULIN LISPRO (HUMALOG MIX 75-25®) *	INSULN PEN
		INSULIN REGULAR, HUMAN (HUMULIN R®)	VIAL
		INSULIN REGULAR, HUMAN (NOVOLIN R®)	VIAL
		INSULIN ZINC HUMAN REC (NOVOLIN L®)	VIAL
		INSULN ASP PRT/INSULIN ASPART (NOVOLOG MIX 70-30®)	VIAL
		INSULN ASP PRT/INSULIN ASPART (NOVOLOG MIX 70-30®) *	INSULN PEN
		NPH, HUMAN INSULIN ISOPHANE (HUMULIN N®)	VIAL
		NPH, HUMAN INSULIN ISOPHANE (HUMULIN N®) *	INSULN PEN
		NPH, HUMAN INSULIN ISOPHANE (NOVOLIN N INNOLET®) *	INSULN PEN
		NPH, HUMAN INSULIN ISOPHANE (NOVOLIN N®)	VIAL
		Endocrine	DM-Oral Hypoglycemics
GLIPIZIDE	TABLET		
GLYBURIDE	TABLET		
METFORMIN HCL	TAB ER 24		
METFORMIN HCL	TAB ER 24H		
METFORMIN HCL	TABLET		
Endocrine	DM-Thiazolidinediones	PIOGLITAZONE HCL (ACTOS®)	TABLET

\* Drug coverage subject to meeting clinical prior authorization criteria.

\*\* Drug coverage subject to quantity limits.

\*\*\*Certain strengths may require Prior Authorization

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred	
Endocrine	Growth Hormone	GENOTROPIN® - BRAND ONLY *	CARTRIDGE
		GENOTROPIN® - BRAND ONLY *	DISP SYRN
		NUTROPIN® - BRAND ONLY *	VIAL
		SAIZEN® - BRAND ONLY *	CARTRIDGE
		SAIZEN® - BRAND ONLY *	VIAL
Endocrine	HRT - Estrogen, Oral	ESTRADIOL	TABLET
		ESTROGENS,CONJ.,SYNTHETIC A (CENESTIN®)	TABLET
		ESTROPIPATE	TABLET
		NORETHIND AC/ETHINYL ESTRADIOL (FEMHRT®)	TABLET
Endocrine	HRT - Estrogen, Topical	ESTRADIOL	PATCH TDWK ***
		ESTRADIOL (ALORA®)	PATCH TDSW ***
		ESTRADIOL (CLIMARA®)	PATCH TDWK ***
Endocrine	HRT - Estrogen, Vaginal	ESTRADIOL (ESTRING®)	VAG RING
		ESTRADIOL (VAGIFEM®)	TABLET
		ESTROGENS, CONJUGATED (PREMARIN®)	CREAM (G)
		ESTROGENS, CONJUGATED (PREMARIN®)	CREAM/APPL
Gastrointestinal	Antiemetics, Newer	ONDANSETRON **	TAB RAPDIS
		ONDANSETRON HCL **	SOLUTION
		ONDANSETRON HCL **	TABLET
Gastrointestinal	Clostridium difficile	METRONIDAZOLE	TABLET
		VANCOMYCIN HCL	CAPSULE
		VANCOMYCIN HCL	VIAL
Gastrointestinal	Digestive Enzymes	CREON®	CAPSULE DR
		PANCRELIPASE®	CAPSULE DR
		ZENPEP®	CAPSULE DR
Gastrointestinal	H2-Antagonists	CIMETIDINE	TABLET
		CIMETIDINE HCL	SOLUTION
		FAMOTIDINE	TABLET
		RANITIDINE HCL	SYRUP
		RANITIDINE HCL	TABLET

\* Drug coverage subject to meeting clinical prior authorization criteria.

\*\* Drug coverage subject to quantity limits.

\*\*\*Certain strengths may require Prior Authorization

**Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012**

<b>System</b>	<b>Class</b>	<b>Preferred</b>	
Gastrointestinal	Inflammatory Bowel	MESALAMINE (APRISO®)	CAP ER 24H
		MESALAMINE (ASACOL®)	TABLET DR ***
		MESALAMINE (ROWASA®)	ENEMA
		MESALAMINE W/CLEANSING WIPES	KIT
		OLSALAZINE SODIUM (DIPENTUM®)	CAPSULE
		SULFASALAZINE (SULFAZINE EC®)	TABLET DR
		SULFASALAZINE (SULFAZINE®)	TABLET
Gastrointestinal	PPIs	OMEPRAZOLE	CAPSULE DR
		OMEPRAZOLE	TABLET DR
		PANTOPRAZOLE SODIUM	TABLET DR
Genitourinary	BPH	DOXAZOSIN MESYLATE	TABLET
		FINASTERIDE	TABLET
		TAMSULOSIN HCL	CAP ER 24H
		TERAZOSIN HCL	CAPSULE
Genitourinary	Overactive Bladder Drugs	FESOTERODINE FUMARATE (TOVIAZ®)	TAB ER 24H
		HYOSCYAMINE SULFATE	DROPS
		HYOSCYAMINE SULFATE (HYOMAX-SR®)	TAB ER 12H
		HYOSCYAMINE SULFATE (HYOSYNE®)	ELIXIR
		OXYBUTYNIN (OXYTROL®)	PATCH TDSW
		OXYBUTYNIN CHLORIDE	SYRUP
		OXYBUTYNIN CHLORIDE	TAB ER 24
		OXYBUTYNIN CHLORIDE	TABLET
		TOLTERODINE TARTRATE (DETROL®)	TABLET
Hematology	Colony Stimulating Factors	FILGRASTIM (NEUPOGEN®)	DISP SYRIN
		FILGRASTIM (NEUPOGEN®)	VIAL
		PEGFILGRASTIM (NEULASTA®)	DISP SYRIN
		SARGRAMOSTIM (LEUKINE®)	VIAL
Hematology	Hematopoietic Agents	DARBEPOETIN ALFA IN POLYSORBAT (ARANESP®) *	VIAL
		EPOGEN® - BRAND ONLY *	VIAL

\* Drug coverage subject to meeting clinical prior authorization criteria.

\*\* Drug coverage subject to quantity limits.

\*\*\*Certain strengths may require Prior Authorization

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred	
Immunologics	Immunosuppressants	AZATHIOPRINE	TABLET ***
		CYCLOSPORINE	CAPSULE
		CYCLOSPORINE (SANDIMMUNE®)	CAPSULE
		CYCLOSPORINE, MODIFIED (GENGRAF®)	CAPSULE
		CYCLOSPORINE, MODIFIED (GENGRAF®)	SOLUTION
		CYCLOSPORINE, MODIFIED (NEORAL®)	CAPSULE
		EVEROLIMUS (ZORTRESS®)	TABLET
		MYCOPHENOLATE MOFETIL	CAPSULE
		MYCOPHENOLATE MOFETIL	TABLET
		MYCOPHENOLATE MOFETIL (CELLCEPT®)	SUSP RECON
		SIROLIMUS (RAPAMUNE®)	SOLUTION
		SIROLIMUS (RAPAMUNE®)	TABLET
		TACROLIMUS (PROGRAF®)	CAPSULE
Immunologics	Targeted Immune Modulators	ADALIMUMAB (HUMIRA®)	KIT
		ADALIMUMAB (HUMIRA®)	PEN IJ KIT
		ETANERCEPT (ENBREL®)	DISP SYRIN
		ETANERCEPT (ENBREL®)	KIT
		ETANERCEPT (ENBREL®)	PEN INJCTR
		INFLIXIMAB (REMICADE®)	VIAL
Neurologic	Alzheimer's Dx	DONEPEZIL HCL (ARICEPT®)	TABLET ***
		GALANTAMINE HBR	TABLET
		MEMANTINE HCL (NAMENDA®)	TABLET

\* Drug coverage subject to meeting clinical prior authorization criteria.

\*\* Drug coverage subject to quantity limits.

\*\*\*Certain strengths may require Prior Authorization

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred	
Neurologic	Anticonvulsants	CARBAMAZEPINE	ORAL SUSP
		CARBAMAZEPINE	TAB CHEW
		CARBAMAZEPINE	TABLET
		CARBAMAZEPINE (TEGRETOL XR®)	TAB ER 12H
		CLONAZEPAM	TABLET
		DIASTAT ACUDIAL® - BRAND ONLY	KIT
		DIASTAT® - BRAND ONLY	KIT
		DIVALPROEX SODIUM	TAB ER 24H
		DIVALPROEX SODIUM	TABLET DR
		DIVALPROEX SODIUM (DEPAKOTE SPRINKLE®)	CAP SPRINK
		ETHOSUXIMIDE	CAPSULE
		ETHOSUXIMIDE	SYRUP
		ETHOTOIN (PEGANONE®)	TABLET
		GABAPENTIN	CAPSULE
		LACOSAMIDE (VIMPAT®)	TABLET
		LAMOTRIGINE	TABLET
		LEVETIRACETAM	TABLET
		LEVETIRACETAM (KEPPRA®)	SOLUTION
		MEPHOBARBITAL (MEBARAL®)	TABLET
		METHSUXIMIDE (CELONTIN®)	CAPSULE
		OXCARBAZEPINE	TABLET
		OXCARBAZEPINE (TRILEPTAL®)	ORAL SUSP
		PHENOBARBITAL	ELIXIR
		PHENOBARBITAL	TABLET
		PHENYTOIN	ORAL SUSP
		PHENYTOIN (DILANTIN®)	TAB CHEW
		PHENYTOIN SODIUM EXTENDED	CAPSULE
		PHENYTOIN SODIUM EXTENDED (DILANTIN®)	CAPSULE
		PHENYTOIN SODIUM EXTENDED (PHENYTEK®)	CAPSULE
		PRIMIDONE	TABLET
		RUFINAMIDE (BANZEL®)	TABLET
		TIAGABINE HCL (GABITRIL®)	TABLET
		TOPIRAMATE *	TABLET
		VALPROIC ACID	CAPSULE
ZONISAMIDE	CAPSULE		
Neurologic	MS Drugs	GLATIRAMER ACETATE (COPAXONE®)	KIT
		INTERFERON BETA-1A (AVONEX®)	KIT
		INTERFERON BETA-1A/ALBUMIN (AVONEX ADMINISTRATION PACK®)	KIT

\* Drug coverage subject to meeting clinical prior authorization criteria.

\*\* Drug coverage subject to quantity limits.

\*\*\*Certain strengths may require Prior Authorization

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred	
Neurologic	Parkinson's Drugs	AMANTADINE HCL	CAPSULE
		AMANTADINE HCL	SYRUP
		AMANTADINE HCL	TABLET
		BENZTROPINE MESYLATE	TABLET
		CARBIDOPA/LEVODOPA	TABLET
		CARBIDOPA/LEVODOPA/ENTACAPONE	TABLET
		ENTACAPONE	TABLET
		PRAMIPEXOLE DI-HCL *	TABLET
		SELEGILINE HCL	CAPSULE
		TRIHEXYPHENIDYL HCL	ELIXIR
		TRIHEXYPHENIDYL HCL	TABLET
Ophthalmic	Antibiotic/Steroid	NEO/POLYMYX B SULF/DEXAMETH	DROPS SUSP
		NEOMY SULF/BACITRAC ZN/POLY/HC	OINT. (G)
		SULFACETM NA/PREDNISOL AC (BLEPHAMIDE S.O.P.®)	OINT. (G)
		SULFACETM NA/PREDNISOL AC (BLEPHAMIDE®)	DROPS SUSP
		TOBRAMYCIN SULF/DEXAMETHASONE	DROPS SUSP
		TOBRAMYCIN SULF/DEXAMETHASONE (TOBRADEX®)	OINT. (G)
Ophthalmic	Antibiotics	BACITRACIN/POLYMYXIN B SULFATE	OINT. (G)
		CIPROFLOXACIN HCL	DROPS
		ERYTHROMYCIN BASE	OINT. (G)
		GENTAMICIN SULFATE	DROPS
		GENTAMICIN SULFATE (GENTAK®)	OINT. (G)
		MOXIFLOXACIN HCL (VIGAMOX®)	DROPS
		NATAMYCIN (NATACYN®)	DROPS SUSP
		NEOMYCIN/POLYMYXIN B/GRAMICIDIN	DROPS
		OFLOXACIN	DROPS
		POLYMYXIN B SULFATE/TMP	DROPS
		SULFACETAMIDE SODIUM	DROPS
		TOBRAMYCIN SULFATE	DROPS
		TOBRAMYCIN SULFATE (TOBREX®)	OINT. (G)

\* Drug coverage subject to meeting clinical prior authorization criteria.

\*\* Drug coverage subject to quantity limits.

\*\*\*Certain strengths may require Prior Authorization

**Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012**

<b>System</b>	<b>Class</b>	<b>Preferred</b>	
Ophthalmic	Anti-Inflammatory Drugs	DEXAMETHASONE (MAXIDEX®)	DROPS SUSP
		DEXAMETHASONE SOD PHOSPHATE	DROPS
		DICLOFENAC SODIUM	DROPS
		FLUOROMETHOLONE	DROPS SUSP ***
		FLUOROMETHOLONE (FML S.O.P®)	OINT. (G)
		FLURBIPROFEN SODIUM	DROPS
		KETOROLAC TROMETHAMINE	DROPS
		LOTEPREDNOL ETABONATE (LOTEMAX®)	DROPS SUSP ***
PREDNISOLONE ACETATE	DROPS SUSP ***		
Ophthalmic	Glaucoma	APRACLONIDINE HCL (IOPIDINE®)	DROPS
		BETAXOLOL HCL	DROPS
		BRIMONIDINE TARTRATE	DROPS ***
		BRINZOLAMIDE (AZOPT®)	DROPS SUSP
		CARTEOLOL HCL	DROPS
		DORZOLAMIDE HCL/TIMOLOL MALEAT	DROPS
		PILOCARPINE HCL (ISOPTO CARPINE®)	DROPS
		PILOCARPINE HCL (PILOPINE HS®)	GEL (GRAM)
		TIMOLOL MALEATE	DROPS
TRAVOPROST (TRAVATAN Z®)	DROPS		
Otic	Antibiotic	CIPROFLOXACIN HCL/DEXAMETH (CIPRODEX®)	DROPS SUSP
		NEOMY SULF/COLIST SUL/HC/THONZ (CORTISPORIN-TC®)	DROPS SUSP
		OFLOXACIN	DROPS
Psychiatric	ADHD	AMPHET ASP/AMPHET/D-AMPHET **	TABLET
		DEXMETHYLPHENIDATE HCL **	TABLET
		DEXTROAMPHETAMINE SULFATE **	TABLET
		LISDEXAMFETAMINE DIMESYLATE (VYVANSE®) **	CAPSULE
		METHYLPHENIDATE HCL (RITALIN LA®)	CPMP 50-50 ***
		METHYLPHENIDATE HCL **	TAB ER 24
		METHYLPHENIDATE HCL **	TABLET
		METHYLPHENIDATE HCL **	TABLET ER
Psychiatric	Sedatives	ZOLPIDEM TARTRATE *	TABLET

\* Drug coverage subject to meeting clinical prior authorization criteria.

\*\* Drug coverage subject to quantity limits.

\*\*\*Certain strengths may require Prior Authorization

**Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List  
Effective July 23, 2012**

<b>System</b>	<b>Class</b>	<b>Preferred</b>	
Pulmonary	Anticholinergic Inhalers	IPRATROPIUM BROMIDE	SOLUTION
		IPRATROPIUM BROMIDE (ATROVENT HFA®)	HFA AER AD
		IPRATROPIUM/ALBUTEROL SULFATE	AMPUL-NEB
		IPRATROPIUM/ALBUTEROL SULFATE (COMBIVENT®)	AER W/ADAP
		TIOTROPIUM BROMIDE (SPIRIVA®)	CAP W/DEV
Pulmonary	Asthma Controllers	BECLOMETHASONE DIPROPIONATE (QVAR®)	AER W/ADAP
		BUDESONIDE (PULMICORT FLEXHALER®)	AER POW BA
		FLUNISOLIDE (AEROBID®)	AER W/ADAP
		FLUTICASONE PROPIONATE (FLOVENT DISKUS®)	DISK W/DEV
		FLUTICASONE PROPIONATE (FLOVENT HFA®)	AER W/ADAP
		FORMOTEROL FUMARATE (FORADIL®)	CAP W/DEV
		MOMETASONE FUROATE (ASMANEX®)	AER POW BA
		MONTELUKAST SODIUM (SINGULAIR®) *	GRAN PACK
		MONTELUKAST SODIUM (SINGULAIR®) *	TAB CHEW
		MONTELUKAST SODIUM (SINGULAIR®) *	TABLET
		SALMETEROL XINAFOATE (SEREVENT DISKUS®)	DISK W/DEV
ZAFIRLUKAST (ACCOLATE®)	TABLET		
Pulmonary	Asthma Rescue	ALBUTEROL SULFATE	SOLUTION
		ALBUTEROL SULFATE	VIAL-NEB
		PIRBUTEROL ACETATE (MAXAIR AUTOHALER®)	AER BR.ACT
		PROAIR HFA® - BRAND ONLY	HFA AER AD
		PROVENTIL HFA® - BRAND ONLY	HFA AER AD
Pulmonary	PAH	BOSENTAN (TRACLEER®) *	TABLET
		SILDENAFIL CITRATE (REVATIO®) *	TABLET ***
		TADALAFIL (ADCIRCA®) *	TABLET ***
Pulmonary	Smoking Cessation	BUPROPION HCL	TABLET ER
		NICOTINE	PATCH DYSQ
		NICOTINE	PATCH TD24 ***
		NICOTINE POLACRILEX	GUM
		NICOTINE POLACRILEX	LOZENGE
		VARENICLINE TARTRATE **	TAB DS PK
		VARENICLINE TARTRATE **	TABLET
Renal	Phosphate Binders	CALCIUM ACETATE	CAPSULE

\* Drug coverage subject to meeting clinical prior authorization criteria.

\*\* Drug coverage subject to quantity limits.

\*\*\*Certain strengths may require Prior Authorization

Table 121-0030-1 Oregon Fee-for-Service Voluntary Mental Health Preferred Drug List  
Effective July 23, 2012

System	Class	Preferred	
Psychiatric	Antidepressants	AMITRIPTYLINE HCL	TABLET
		BUPROPION HCL	TABLET
		BUPROPION HCL	TABLET ER
		CITALOPRAM HYDROBROMIDE **	SOLUTION
		CITALOPRAM HYDROBROMIDE **	TABLET
		CLOMIPRAMINE HCL	CAPSULE
		DOXEPIN HCL	CAPSULE
		FLUOXETINE HCL	CAPSULE
		FLUOXETINE HCL	SOLUTION
		FLUOXETINE HCL	TABLET
		FLUVOXAMINE MALEATE	TABLET
		LEXAPRO® - BRAND ONLY	SOLUTION
		LEXAPRO® - BRAND ONLY	TABLET
		MIRTAZAPINE	TAB RAPDIS
		MIRTAZAPINE	TABLET
		NORTRIPTYLINE HCL	CAPSULE
		NORTRIPTYLINE HCL	SOLUTION
		PAROXETINE HCL	TABLET
		SERTRALINE HCL	ORAL CONC
		SERTRALINE HCL	TABLET
VENLAFAXINE HCL	CAP ER 24H		
VENLAFAXINE HCL	TABLET		
Psychiatric	Antipsychotics - 2nd Generation	CLOZAPINE	TABLET
		GEODON® - BRAND ONLY	CAPSULE
		QUETIAPINE FUMARATE (SEROQUEL®) *	TABLET
		RISPERIDONE	SOLUTION
		RISPERIDONE	TAB RAPDIS
		RISPERIDONE	TABLET

\* Drug coverage subject to meeting clinical prior authorization criteria.

\*\* Drug coverage subject to quantity limits.

\*\*\*Certain strengths may require Prior Authorization

## **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 Oregon Health Plan (OHP) in a manner consistent with the Oregon Health Services Commission's Prioritized List of Health Services (OAR 410-141-0480 through 410-141-0520). If the medication is for a non-covered diagnosis, the medication shall not be covered unless there is a co-morbid condition for which coverage would be extended. The use of the medication must meet corresponding treatment guidelines, be 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 Oregon Health Authority (Authority) 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 that the Authority requires PA for this purpose are found in the OHP Fee-For-Service Pharmacy PA Criteria Guide (PA Criteria Guide) dated ~~June 21, 2014~~ July 23, 2012, incorporated in rule by reference and found on our Web page at:

<http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html>

(4) The Authority 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 Pharmacy & Therapeutics Committee

(P&T) and adopted by the Authority in this rule (see OAR 410-121-0100 for a description of the DUR program). The drugs and categories of drugs for which the Authority requires PA for this purpose are found in the Pharmacy PA Criteria Guide.

(5) New drugs shall be evaluated when added to the weekly upload of the First DataBank drug file:

(a) If the new drug is in a class where current PA criteria apply, all associated PA criteria shall be required at the time of the drug file load;

(b) If the new drug is indicated for a condition below the funding line on the Prioritized List of Health Services, PA shall be required to ensure that the drug is prescribed for a condition funded by OHP;

(c) PA criteria for all new drugs shall be reviewed by the DUR/P&T Committee.

(6) PA is required for brand name drugs that have two or more generically equivalent products available and that are NOT determined Narrow Therapeutic Index drugs by the Oregon DUR/P&T Committee:

(a) Immunosuppressant drugs used in connection with an organ transplant must be evaluated for narrow therapeutic index within 180 days after United States patent expiration;

(b) Manufacturers of immunosuppressant drugs used in connection with an organ transplant must notify the department of patent expiration within 30 days of patent expiration for (5)(a) to apply;

(c) Criteria for approval are:

(A) If criteria established in subsection (3) or (4) of this rule applies, follow that criteria;

(B) If (6)(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.

(7) PA is required for non-preferred Preferred Drug List (PDL) products in a class evaluated for the PDL except in the following cases:

(a) The drug is a mental health drug as defined in OAR 410-121-0000;

(b) The original prescription is written prior to 1/1/10;

(c) The prescription is a refill for the treatment of seizures, cancer, HIV or AIDS; or

(d) The prescription is a refill of an immunosuppressant.

(8) PA may not be required:

(a) When the prescription ingredient cost plus the dispensing fee is less than the PA processing fees as determined by the Authority;

(b) For over-the-counter (OTC) covered drugs when prescribed for conditions covered under OHP or;

(c) If a drug is in a class not evaluated from the Practitioner-Managed Prescription Drug Plan under ORS 414.334.

Stat. Auth.: ORS Chap. 409.110, 413.042, 414.325, 414.065, and 414.334

Stats. Implemented: 414.065

7-23-12 (T)

## Amylin Analog

**Initiative:**

- To optimize the correct use of amylin analogs.

**Length of Authorization:**

Up to 12 months

**Requires PA:**

- Non-preferred drugs
- Pramlintide (Symlin®)

**Covered Alternatives:**

Preferred alternatives listed at [http://www.oregon.gov/DHS/healthplan/tools\\_prov/pdl.shtml](http://www.oregon.gov/DHS/healthplan/tools_prov/pdl.shtml)

Approval Criteria		
1. Does the patient have a diagnosis of Type 1 diabetes <u>and is taking mealtime insulin</u> ?	Yes: Approve for 12 months.	No: Go to #2
2. Does the patient have Type 2 diabetes <u>and is taking mealtime insulin</u> ?	Yes: Go to #3	No: Pass to RPh; Deny based on appropriateness of therapy.
3. Will the prescriber consider a change to a preferred product? Message: <ul style="list-style-type: none"> <li>Preferred products do not require PA.</li> <li>Preferred products are evidence-based reviewed for comparative effectiveness &amp; safety by the Health Resources Commission (HRC).</li> </ul>	Yes: Inform provider of covered alternatives in class.	No: Go to #4.
4. Has the patient tried and failed metformin <u>and sulfonylurea</u> therapy or have contraindications to <u>these treatments metformin therapy</u> ? <ul style="list-style-type: none"> <li>Contraindications include:</li> <li>Renal disease or renal dysfunction</li> <li>Known hypersensitivity to metformin <u>and/or sulfonylureas</u></li> <li>Acute or chronic metabolic acidosis</li> <li>Patients at increased risk of lactic acidosis (CHF, advanced age, impaired hepatic function)</li> </ul>	Yes: Approve for up to 12 months.	No: Deny. Recommend trial of metformin or sulfonylurea. See below for metformin titration schedule.

## Initiating Metformin

1. Begin with low-dose metformin (500 mg) taken once or twice per day with meals (breakfast and/or dinner) or 850 mg once per day.
2. After 5-7 days, if gastrointestinal side effects have not occurred, advance dose to 850 mg, or two 500 mg tablets, twice per day (medication to be taken before breakfast and/or dinner).
3. If gastrointestinal side effects appear as doses advanced, decrease to previous lower dose and try to advance the dose at a later time.
4. The maximum effective dose can be up to 1,000 mg twice per day but is often 850 mg twice per day. Modestly greater effectiveness has been observed with doses up to about 2,500 mg/day. Gastrointestinal side effects may limit the dose that can be used.

Nathan, et al. Medical Management of Hyperglycemia in Type 2 Diabetes; A Consensus Algorithm for the Initiation and Adjustment of Therapy. Diabetes Care 31; 1-11, 2008.

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*P&T / DUR Action:* [4/26/12 \(KS\)](#), 3/17/11(KS)

*Revision(s):*

*Initiated:* [7/16/12](#), 1/1/12

## Fidaxomicin (Difcid®)

**Goal(s):**

- To optimize appropriate treatment of Clostridium difficile associated diarrhea

**Length of Authorization:**

10 days

**Requires PA:**

- Non-preferred drugs
- Fixaxomicin (Difcid®)

**Covered Alternatives:**Preferred alternatives listed at [http://www.oregon.gov/DHS/healthplan/tools\\_prov/pdl.shtml](http://www.oregon.gov/DHS/healthplan/tools_prov/pdl.shtml)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Does the patient have a diagnosis of Clostridium Difficile Associated Diarrhea (CDAD)? (ICD-9 008.45)?	Yes: Go to #3.	No: Pass to RPH; Deny (medical appropriateness)
3. Will the prescriber consider a change to a preferred antibiotic?  Message: • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics Committee.	Yes: Inform Provider of covered alternatives in class.	No: Go to #4
4. Does the patient have a documented trial of appropriate therapy with vancomycin or metronidazole for a first recurrence or contraindication to therapy?	Yes: Go to #5.	No: Pass to RPH; Deny (medical appropriateness)
5. Does the patient have severe, complicated CDAD (life-threatening or fulminant infection or toxic megacolon)?	Yes: Pass to RPH; Deny (medical appropriateness)	No: Approve for up to 10 days

P&T / DUR Action: 4/26/12  
Revision(s):  
Initiated: 7/23/12

## Hepatitis B Antivirals

### Goal(s):

- Cover hepatitis B agents according to OHP guidelines. Cover preferred products when feasible for covered diagnosis.
- Preferred products are selected based on evidence based reviews.

### Length of Authorization:

Up to 12 months; quantity limited to a 30 day supply per dispensing.

### Requires PA:

- Non-preferred drugs

### Covered Alternatives:

Preferred alternatives listed at [http://www.oregon.gov/DHS/healthplan/tools\\_prov/pdl.shtml](http://www.oregon.gov/DHS/healthplan/tools_prov/pdl.shtml)

### Pediatric Age Restrictions:

- lamivudine (Epivir HBV) - 2 years and up
- adefovir dipivoxil (Hepsera) - 12-17 years
- entecavir (Baraclude) - 16 years and up
- telbivudine (Tyzeka) - safety and effectiveness not approved in pediatrics

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is the diagnosis an OHP covered diagnosis?	Yes: Go to #3.	No: Pass to RPh, Deny for OHP Coverage.
3. Is the request for treatment of Chronic Hepatitis B?	Yes: Go to #4	No: Pass to RPh, Deny for Appropriateness
4. Is this a continuation of current therapy (i.e. filled prescription within prior 90 days)? Verify via pharmacy claims. ***If request is for Pegasys, refer to PA criteria "Pegylated Interferon and Ribavirin."***	Yes: Go to Renewal Criteria	No: Go to #5
5. Has the client tried and is intolerant to, resistant to, or has a contraindication to the preferred products?	Yes: Document intolerance or contraindication. Approve requested treatment for 6 months with monthly quantity limit of 30 day's supply.	No: Go to #6

## NEW CRITERIA

### Approval Criteria

6. Will the prescriber consider a change to a preferred product?	Yes: Inform provider of covered alternatives in class.	No: Approve requested treatment for 6 months with monthly quantity limit of 30 day's supply.
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### Renewal Criteria

1. Is client compliant with requested treatment (see refill history)?	Yes: Go to 2.
2. Is HBV DNA undetectable?	Yes: Approve for up to 1 year with monthly quantity limit of 30 day's supply

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*P&T / DUR Action:* 4/26/12

*Revision(s):*

*Initiated:* 7/23/12

## Incretin Enhancers

### Initiative:

- Optimize correct use that corresponds to National Guidelines of incretin enhancers.

### Length of Authorization:

Up to 12 months

### Requires PA:

- Non-preferred drugs
- Sitagliptin (Januvia®)
- Sigagliptin/metformin (Janumet®)
- Saxaglitptin (Onglyza®)
- Saxagliptin/metformin (Kombiglyze XR®)
- Linagliptin (Tradjenta®)
- Linagliptin/metformin (Jentadueto®)

### Covered Alternatives:

Preferred alternatives listed at [http://www.oregon.gov/DHS/healthplan/tools\\_prov/pdl.shtml](http://www.oregon.gov/DHS/healthplan/tools_prov/pdl.shtml)

### Approval Criteria

1. Does the patient have a diagnosis of Type 2 diabetes?	Yes: Go to #2	No: Deny based on appropriateness of therapy.
2. Will the prescriber consider a change to a preferred product?  Message: Preferred products do not require PA. Preferred products are evidence-based reviewed for comparative effectiveness & safety by the Health Resources Commission (HRC).	Yes: Inform provider of covered alternatives in class.	No: Go to #3.

## Approval Criteria

<p>3. Has the patient tried and failed metformin and sulfonylurea therapy or have contraindications to these treatments?</p> <p>Contraindications include:</p> <ul style="list-style-type: none"><li>• Renal disease or renal dysfunction</li><li>• Known hypersensitivity to therapies</li><li>• Acute or chronic metabolic acidosis</li><li>• Patients at increased risk of lactic acidosis (CHF, advanced age, impaired hepatic function)</li></ul>	Yes: Approve for up to 12 months.	No: Recommend trial of metformin or sulfonylurea. See below for metformin titration schedule.
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## Initiating Metformin

1. Begin with low-dose metformin (500 mg) taken once or twice per day with meals (breakfast and/or dinner) or 850 mg once per day.
2. After 5-7 days, if gastrointestinal side effects have not occurred, advance dose to 850 mg, or two 500 mg tablets, twice per day (medication to be taken before breakfast and/or dinner).
3. If gastrointestinal side effects appear as doses advanced, decrease to previous lower dose and try to advance the dose at a later time.
4. The maximum effective dose can be up to 1,000 mg twice per day but is often 850 mg twice per day. Modestly greater effectiveness has been observed with doses up to about 2,500 mg/day. Gastrointestinal side effects may limit the dose that can be used.

Nathan, et al. Medical Management of Hyperglycemia in Type 2 Diabetes; A Consensus Algorithm for the Initiation and Adjustment of Therapy. Diabetes Care 31;1-11, 2008.

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*P&T / DUR Action:* 4/26/12 (KS), 3/17/11 (KS)

*Revision(s):*

*Initiated:* 7/23/12, 1/1/12

## Incretin Mimetics

**Initiative:**

- To optimize the correct use of insulin mimetics.

**Length of Authorization:**

Up to 12 months

**Requires PA:**

- ~~Non-preferred drugs~~ Exenatide (Byetta), liraglutide (Victoza) and exenatide extended-release (Bydureon)

**Covered Alternatives:**

Preferred alternatives listed at [http://www.oregon.gov/DHS/healthplan/tools\\_prov/pdl.shtml](http://www.oregon.gov/DHS/healthplan/tools_prov/pdl.shtml)

Approval Criteria		
1. Does the patient have a diagnosis of Type 2 diabetes?	Yes: Go to #2	No: Deny based on appropriateness of therapy.
2. Will the prescriber consider a change to a preferred product?  Message: Preferred products do not require PA. Preferred products are evidence-based reviewed for comparative effectiveness & safety by the Health Resources Commission (HRC).	Yes: Inform provider of covered alternatives in class.	No: Go to #3.
3. Has the patient tried and failed metformin <u>and sulfonylurea</u> therapy or have contraindications to <del>these treatments</del> <u>metformin therapy</u> ? Contraindications include: <ul style="list-style-type: none"> <li>Renal disease or renal dysfunction</li> <li>Known hypersensitivity to <del>these treatments</del><u>metformin</u></li> <li>Acute or chronic metabolic acidosis</li> <li>Patients at increased risk of lactic acidosis (CHF, advanced age, impaired hepatic function)</li> </ul>	Yes: Go to #4.	No: Deny. Recommend trial of metformin <u>or sulfonylurea</u> . See below for <u>metformin</u> titration schedule.

## Approval Criteria

4. Is the patient currently taking insulin?	Yes: <del>Go to #5 Deny. The safety and efficacy of this combination has not been studied.</del>	No: Approve for up to 12 months.
5. Is the patient requesting exenatide (Byetta®) and is taking insulin glargine?	Yes: Approve for up to 12 months.	No: Pass to RPH; deny (medical appropriateness). The safety and efficacy of other insulin formulations and GLP-1 Agonists have not been studied.

## Initiating Metformin

1. Begin with low-dose metformin (500 mg) taken once or twice per day with meals (breakfast and/or dinner) or 850 mg once per day.
2. After 5-7 days, if gastrointestinal side effects have not occurred, advance dose to 850 mg, or two 500 mg tablets, twice per day (medication to be taken before breakfast and/or dinner).
3. If gastrointestinal side effects appear as doses advanced, decrease to previous lower dose and try to advance the dose at a later time.
4. The maximum effective dose can be up to 1,000 mg twice per day but is often 850 mg twice per day. Modestly greater effectiveness has been observed with doses up to about 2,500 mg/day. Gastrointestinal side effects may limit the dose that can be used.

Nathan, et al. Medical Management of Hyperglycemia in Type 2 Diabetes; A Consensus Algorithm for the Initiation and Adjustment of Therapy. Diabetes Care 31;1-11, 2008.

P&T / DUR Action: [4/26/12 \(KS\)](#), 3/17/11 (KS)

Revision(s):

Initiated: [7/16/12](#), 1/1/12

## Ivacaftor (Kalydeco®)

**Goal(s):**

- To ensure appropriate drug use and limit to patient populations in which the drug has been shown to be effective and safe.

**Length of Authorization:**

Up to 12 months

**Requires PA:**

- Non-preferred drugs
- Ivacaftor (Kalydeco®)

**Approval Criteria**

1. What diagnosis is being treated?	Record ICD9 code.	
2. Does the client have a diagnosis of cystic fibrosis and is 6 years of age or older?	Yes: Go to #3.	No: Pass to RPH; Deny (medical appropriateness)
3. Does the patient have a documented G551D mutation in the CFTR gene?  • If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the G551D mutation.	Yes: Go to #4.	No: Pass to RPH; Deny (medical appropriateness)
4. Is the prescription for ivacaftor 150mg twice daily, once daily or twice-a-week?	Yes: Approve for one year.	No: Pass to RPH; Deny (medical appropriateness)

**Limitations of Use:**

- Ivacaftor is not effective in patients with Cystic Fibrosis who are homozygous for the F508del mutation in the CFTR gene.
- Ivacaftor has not been studied in other populations of patients with Cystic Fibrosis.

**References:**

- Kalydeco [package insert]. Vertex Pharmaceuticals Inc., Cambridge, MA; January 2012. [http://pi.vrtx.com/files/uspi\\_ivacaftor.pdf](http://pi.vrtx.com/files/uspi_ivacaftor.pdf).
- Kalydeco™ (ivacaftor) for the Management of Cystic Fibrosis. Formulary Submission Dossier. Vertex Pharmaceuticals. February 2012.
- Ramsey B., Davies J., McElvaney G., et al. A CFTR Potentiator in Patients with Cystic Fibrosis and the G551D Mutation. N Engl J Med 365;18. November 3, 2011
- Flume PA, Liou TG, Borowitz DS, et al. Ivacaftor in subjects with cystic fibrosis who are homozygous for the F508del-CFTR mutation. Chest. 2012 Mar 1. [Epub ahead of print]

P&T / DUR Action: 4/26/12 (MH/KS)  
Revision(s):  
Initiated: 7/23/12

## Smoking Cessation

**Goal(s):**

- Promote use that is consistent with National Guidelines and medical evidence.
- Promote use of high value products

**Length of Authorization:**

3-6 months

**Requires PA:**

- Non-preferred drugs
- NRT beyond 6 months in the absence of behavioral counseling
- Varenicline beyond 12 weeks

**Covered Alternatives:**Preferred alternatives listed at [http://www.oregon.gov/DHS/healthplan/tools\\_prov/pdl.shtml](http://www.oregon.gov/DHS/healthplan/tools_prov/pdl.shtml)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is the diagnosis for tobacco dependence? (ICD-9 305.1)?	Yes: Go to #3	No: Pass to RPH; Deny (medical appropriateness)
3. Is the request for a preferred NRT?	Yes: Go to #5	No: Go to #4
4. Is the request for varenicline?	Yes: Go to #5	No: Go to #7
5. Has patient quit?	Yes: Approve varenicline x 12 additional weeks	No: Go to #6
6. Is the patient enrolled in a smoking cessation behavioral counseling program (e.g. Quit Line at: 800 – xxx-xxxx).	Yes: Approve NRT x 6 additional months or Approve varenicline x 12 additional weeks	No: Pass to RPH; Deny (medical appropriateness)

<b>Approval Criteria</b>		
<p>7. Will the prescriber consider a change to a preferred product?</p> <p>Message:</p> <ul style="list-style-type: none"> <li>• Preferred products do not require a PA for initial treatment.</li> <li>• Preferred products are evidence based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&amp;T) Committee. Reports are available at:  <a href="http://pharmacy.oregonstate.edu/drug_policy/reviews">http://pharmacy.oregonstate.edu/drug_policy/reviews</a></li> </ul>	<p>Yes: Inform provider of covered alternatives in class</p>	<p>No: Approve treatment for up to 6 months</p>

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*DUR/P&T Action:*      4/26/12  
*Revision(s):*  
*Initiated:*              7/23/12

## Tesamorelin (Egrifta®)

**Goal(s):**

- Cover for only OHP covered diagnoses
- Restrict to indications supported by medical literature

**Requires PA:**

- Tesamorelin (Egrifta®)

### Approval Criteria

1. What diagnosis is being treated?	Record ICD9 code.	
2. Is the diagnosis an OHP covered diagnosis?	Yes: Go to #3	No: Pass to RPH; Deny, (Not covered by the OHP).
3. Is the diagnosis a reduction of excess abdominal fat in HIV-infected patients with lipodystrophy?	Yes: Pass to RPH; Deny, (Not covered by the OHP).	No: Pass to RPH; Deny (medical appropriateness).

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*P&T / DUR Action:*      4/26/12  
*Revision(s):*  
*Initiated:*                7/23/12