

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 – June 28, 2012 DUR/P&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 temporarily amended 410-121-0030(T) and 410-121-0040(T) per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made in the June 28, 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:

- Make Lovaza non-preferred in the Cardiovascular Other Lipid Lowering Agents drug class
- Add Cardiovascular, Anti-Anginals to the PDL, making nitroglycerin sublingual tablets, isosorbide dinitrate tablets, isosorbide mononitrate tablets, isosorbide mononitrate ER 24H tablets, isosorbide dinitrate ER capsules, nitroglycerin ER capsules and nitroglycerine patches preferred. Make isosorbide dinitrate ER tablets, nitroglycerin spray and ointments, including nitroglycerin ointment 0.4% (Rectiv®) non-preferred.
- Make peginesatide (Omontys®) non-preferred
- Make golimumab, tocilizumab and ustekinumab non-preferred in the Immunologics, Targeted Immune Modulators drug class
- Make deferoxamine (Ferriprox®) preferred

410-121-0040:

- Ivacaftor (Kalydeco®) – criteria re-written
- Erythropoiesis Stimulating Agents (ESAs) – criteria re-written

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

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

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Rules Coordinator Address Telephone

to become effective [9/24/12] 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 – June 28, 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: 410-121-0030 (T) & 410-121-0040(T)

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:

- Make Lovaza non-preferred in the Cardiovascular Other Lipid Lowering Agents drug class
- Add Cardiovascular, Anti-Anginals to the PDL, making sublingual tablets, isosorbid dinitrate tablets, isosorbide mononitrate tablets, isosorbide dinitrate ER, isosorbide mononitrate ER 24H tablets, isosorbide dinitrate ER capsules, nitroglycerin ER capsules and nitroglycerine patches preferred. Make isosorbide dinitrate ER tablets, nitroglycerin spray and ointments, including nitroglycerin ointment 0.4% (Rectiv®) non-preferred.
- Make peginesatide (Omontys®) non-preferred
- Make golimumab, tocilizumab and ustekinumab non-preferred in the Immunologics, Targeted Immune Modulators drug class
- Make deferoxamine (Ferriprox®) preferred

410-121-0040:

- Ivacaftor (Kalydeco®) – criteria re-written
- Erythropoiesis Stimulating Agents (ESAs) – criteria re-written

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

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

9-26-12 (T)

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective September 24, 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 * 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 September 24, 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	Triptans, Injection	IMITREX® - BRAND ONLY **	CARTRIDGE
		IMITREX® - BRAND ONLY **	PEN INJCTR
		IMITREX® - BRAND ONLY **	VIAL
Analgesics	Triptans, Nasal	IMITREX® - BRAND ONLY **	SPRAY
		ZOLMITRIPTAN **	SPRAY
Analgesics	Triptans, 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

* Drug coverage subject to meeting clinical prior authorization criteria.

** Drug coverage subject to quantity limits.

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Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective September 24, 2012

System	Class	Preferred
Antibiotics	Fluoroquinolones, Oral	CIPROFLOXACIN 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 TABLET DR ERYTHROMYCIN ETHYLSUCCINATE ORAL SUSP ERYTHROMYCIN ETHYLSUCCINATE SUSP RECON ERYTHROMYCIN ETHYLSUCCINATE TABLET ERYTHROMYCIN STEARATE TABLET
Antibiotics	Tetracyclines, Oral	DOXYCYCLINE HYCLATE CAPSULE DOXYCYCLINE HYCLATE TABLET DOXYCYCLINE MONOHYDRATE CAPSULE *** DOXYCYCLINE MONOHYDRATE 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 * SOLUTION LAMIVUDINE * TABLET TENOFVIR DISOPROXIL FUMARATE * TABLET
Antiviral	Hepatitis C	BOCEPREVIR * CAPSULE PEGINTERFERON ALFA-2A(PEGASYS®) * KIT PEGINTERFERON ALFA-2B * KIT *** PEGINTERFERON ALFA-2B * PEN IJ KIT RIBAVIRIN * CAPSULE RIBAVIRIN * TABLET TELAPREVIR * TABLET

* Drug coverage subject to meeting clinical prior authorization criteria.

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Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective September 24, 2012

System	Class	Preferred
Antiviral	HSV, Oral	ACYCLOVIR CAPSULE ACYCLOVIR ORAL SUSP ACYCLOVIR TABLET
Antiviral	Influenza	AMANTADINE HCL CAPSULE AMANTADINE HCL SYRUP AMANTADINE HCL TABLET OSELTAMIVIR PHOSPHATE ** CAPSULE OSELTAMIVIR PHOSPHATE ** SUSP RECON RIMANTADINE HCL TABLET
Cardiovascular	Anti-Anginals	ISOSORBIDE DINITRATE CAPSULE ER ISOSORBIDE DINITRATE TABLET ISOSORBIDE MONONITRATE TABLET NITROGLYCERIN CAPSULE ER NITROGLYCERIN PATCH TD24 NITROGLYCERIN TAB SUBL
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

* Drug coverage subject to meeting clinical prior authorization criteria.

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**Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective September 24, 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 TRANDOLAPRIL 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 TABLET QUINAPRIL/HYDROCHLOROTHIAZIDE TABLET TELMISARTAN/HYDROCHLOROTHIAZIDE 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 September 24, 2012

System	Class	Preferred	
Cardiovascular	Other Lipid Lowering Agents	CHOLESTYRAMINE (WITH SUGAR)	PACKET
		CHOLESTYRAMINE (WITH SUGAR)	POWDER
		CHOLESTYRAMINE/ASPARTAME	PACKET
		CHOLESTYRAMINE/ASPARTAME	POWDER
		FENOFIBRATE	TABLET
		GEMFIBROZIL	TABLET
		NIACIN	TAB ER 24H
		NIACIN	TABLET
Cardiovascular	Platelet Inhibitors	ASPIRIN	TABLET
		ASPIRIN/DIPYRIDAMOLE(AGGRENOX®)	CPMP 12HR
		CLOPIDOGREL BISULFATE	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 *	CREAM (G)
		CALCIPOTRIENE *	SOLUTION
		CALCIPOTRIENE/BETAMETHASONE *	OINT. (G)
		TAZAROTENE(TAZORAC®) *	CREAM (G)
		TAZAROTENE(TAZORAC®) *	GEL (GRAM)

* 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 September 24, 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 *	GEL (GRAM)
		TESTOSTERONE *	GEL PACKET
		TESTOSTERONE *	PATCH TD24
		TESTOSTERONE CYPIONATE	VIAL
		TESTOSTERONE ENANTHATE	VIAL
Endocrine	Bone Metabolism Drugs	ALENDRONATE SODIUM	TABLET
		ALENDRONATE SODIUM/VITAMIN D3	TABLET
		IBANDRONATE SODIUM	TABLET
Endocrine	DM-Amylin Analogs	PRAMLINTIDE ACETATE(SYMLINPEN®) *	PEN INJCTR

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** 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 September 24, 2012

System	Class	Preferred	
Endocrine	DM-Insulin	HUM INSULIN NPH/REG INSULIN HM	VIAL
		HUM INSULIN NPH/REG INSULIN HM *	INSULN PEN
		INSULIN ASPART	VIAL
		INSULIN ASPART *	CARTRIDGE
		INSULIN ASPART *	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	VIAL
		INSULIN LISPRO *	CARTRIDGE
		INSULIN LISPRO *	INSULN PEN
		INSULIN NPL/INSULIN LISPRO	VIAL
		INSULIN NPL/INSULIN LISPRO *	INSULN PEN
		INSULIN REGULAR, HUMAN	VIAL
		INSULIN ZINC HUMAN REC	VIAL
		INSULN ASP PRT/INSULIN ASPART	VIAL
		INSULN ASP PRT/INSULIN ASPART *	INSULN PEN
		NPH, HUMAN INSULIN ISOPHANE	VIAL
NPH, HUMAN INSULIN ISOPHANE *	INSULN PEN		
Endocrine	DM-Oral Hypoglycemics	GLIMEPIRIDE	TABLET
		GLIPIZIDE	TABLET
		GLYBURIDE	TABLET
		METFORMIN HCL	TAB ER 24
		METFORMIN HCL	TAB ER 24H
		METFORMIN HCL	TABLET
Endocrine	DM-Thiazolidinediones	PIOGLITAZONE HCL	TABLET
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	TABLET
		ESTROPIPATE	TABLET
		NORETHIND AC/ETHINYL ESTRADIOL	TABLET

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***Certain strengths may require Prior Authorization

Table 121-0030-1 Oregon Fee-for-Service Enforceable Physical Health Preferred Drug List
Effective September 24, 2012

System	Class	Preferred	
Endocrine	HRT - Estrogen, Topical	ESTRADIOL ESTRADIOL ESTRADIOL ESTRADIOL ESTROGENS, CONJUGATED ESTROGENS, CONJUGATED	PATCH TDSW *** PATCH TDWK *** TABLET VAG RING CREAM (G) CREAM/APPL
Endocrine	HRT - Estrogen, Vaginal	ESTRADIOL ESTRADIOL ESTROGENS, CONJUGATED ESTROGENS, CONJUGATED	PATCH TDSW *** PATCH TDWK *** TABLET VAG RING CREAM (G) CREAM/APPL
Gastrointestinal	Antiemetics, Newer	ONDANSETRON ONDANSETRON HCL ONDANSETRON HCL	TAB RAPDIS SOLUTION TABLET
Gastrointestinal	Clostridium difficile	METRONIDAZOLE VANCOMYCIN HCL VANCOMYCIN HCL	TABLET CAPSULE VIAL
Gastrointestinal	Digestive Enzymes	CREON LIPASE/PROTEASE/AMYLASE ZENPEP	CAPSULE DR CAPSULE DR CAPSULE DR
Gastrointestinal	H2-Antagonists	CIMETIDINE CIMETIDINE HCL FAMOTIDINE RANITIDINE HCL RANITIDINE HCL	TABLET SOLUTION TABLET SYRUP TABLET
Gastrointestinal	Inflammatory Bowel	MESALAMINE MESALAMINE MESALAMINE W/CLEANSING WIPES MESALAMINE(APRISO®) OLSALAZINE SODIUM SULFASALAZINE SULFASALAZINE	ENEMA TABLET DR *** KIT CAP ER 24H CAPSULE TABLET TABLET DR
Gastrointestinal	PPIs	OMEPRAZOLE OMEPRAZOLE PANTOPRAZOLE SODIUM	CAPSULE DR TABLET DR TABLET DR

* 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 September 24, 2012

System	Class	Preferred	
Genitourinary	BPH	DOXAZOSIN MESYLATE	TABLET
		FINASTERIDE	TABLET
		TAMSULOSIN HCL	CAP ER 24H
		TERAZOSIN HCL	CAPSULE
Genitourinary	Overactive Bladder Drugs	FESOTERODINE FUMARATE	TAB ER 24H
		HYOSCYAMINE SULFATE	DROPS
		HYOSCYAMINE SULFATE	ELIXIR
		HYOSCYAMINE SULFATE	TAB ER 12H
		OXYBUTYNIN	PATCH TDSW
		OXYBUTYNIN CHLORIDE	SYRUP
		OXYBUTYNIN CHLORIDE	TAB ER 24
		OXYBUTYNIN CHLORIDE	TABLET
		TOLTERODINE TARTRATE	TABLET
Hematology	Colony Stimulating Factors	FILGRASTIM	DISP SYRIN
		FILGRASTIM	VIAL
		PEGFILGRASTIM	DISP SYRIN
		SARGRAMOSTIM	VIAL
Hematology	Hematopoietic Agents	DARBEPOETIN ALFA IN POLYSORBAT(ARANESP®)	DISP SYRIN
		DARBEPOETIN ALFA IN POLYSORBAT(ARANESP®) *	VIAL
		EPOGEN® - BRAND ONLY *	VIAL
Hematology	Iron Chelators	DEFEROXAMINE MESYLATE	VIAL
Immunologics	Immunosuppressants	AZATHIOPRINE	TABLET ***
		CYCLOSPORINE	CAPSULE
		CYCLOSPORINE, MODIFIED	CAPSULE
		CYCLOSPORINE, MODIFIED	SOLUTION
		EVEROLIMUS	TABLET
		MYCOPHENOLATE MOFETIL	CAPSULE
		MYCOPHENOLATE MOFETIL	SUSP RECON
		MYCOPHENOLATE MOFETIL	TABLET
		SIROLIMUS	SOLUTION
		SIROLIMUS	TABLET
		TACROLIMUS	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 Enforceable Physical Health Preferred Drug List
Effective September 24, 2012

System	Class	Preferred	
Immunologics	Targeted Immune Modulators	ADALIMUMAB(HUMIRA®)	KIT
		ADALIMUMAB(HUMIRA®)	PEN IJ KIT
		ETANERCEPT(ENBREL®)	DISP SYRIN
		ETANERCEPT(ENBREL®)	KIT
		ETANERCEPT(ENBREL®)	PEN INJCTR
		INFLIXIMAB	VIAL
Neurologic	Alzheimer's Dx	DONEPEZIL HCL	TABLET ***
		GALANTAMINE HBR	TABLET
		MEMANTINE 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 September 24, 2012

System	Class	Preferred	
Neurologic	Anticonvulsants	CARBAMAZEPINE	ORAL SUSP
		CARBAMAZEPINE	TAB CHEW
		CARBAMAZEPINE	TAB ER 12H
		CARBAMAZEPINE	TABLET
		CLONAZEPAM	TABLET
		DIASTAT ACUDIAL® - BRAND ONLY	KIT
		DIASTAT® - BRAND ONLY	KIT
		DIVALPROEX SODIUM	CAP SPRINK
		DIVALPROEX SODIUM	TAB ER 24H
		DIVALPROEX SODIUM	TABLET DR
		ETHOSUXIMIDE	CAPSULE
		ETHOTOIN	TABLET
		GABAPENTIN	CAPSULE
		LACOSAMIDE	TABLET
		LAMOTRIGINE	TABLET
		LEVETIRACETAM	SOLUTION
		LEVETIRACETAM	TABLET
		MEPHOBARBITAL	TABLET
		METHSUXIMIDE	CAPSULE
		OXCARBAZEPINE	ORAL SUSP
		OXCARBAZEPINE	TABLET
		PHENOBARBITAL	ELIXIR
		PHENOBARBITAL	TABLET
		PHENYTOIN	ORAL SUSP
		PHENYTOIN	TAB CHEW
		PHENYTOIN SODIUM EXTENDED	CAPSULE
		PRIMIDONE	TABLET
		RUFINAMIDE	TABLET
		TIAGABINE HCL	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 September 24, 2012

System	Class	Preferred	
Neurologic	Parkinson's Drugs	AMANTADINE HCL	CAPSULE
		AMANTADINE HCL	SYRUP
		AMANTADINE HCL	TABLET
		BENZTROPINE MESYLATE	TABLET
		CARBIDOPA/LEVODOPA	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	DROPS SUSP
		SULFACETM NA/PREDNISOL AC	OINT. (G)
		TOBRAMYCIN SULF/DEXAMETHASONE	DROPS SUSP
		TOBRAMYCIN SULF/DEXAMETHASONE	OINT. (G)
Ophthalmic	Antibiotics	BACITRACIN/POLYMYXIN B SULFATE	OINT. (G)
		CIPROFLOXACIN HCL	DROPS
		ERYTHROMYCIN BASE	OINT. (G)
		GENTAMICIN SULFATE	DROPS
		GENTAMICIN SULFATE	OINT. (G)
		MOXIFLOXACIN HCL(VIGAMOX®)	DROPS
		NATAMYCIN	DROPS SUSP
		NEOMYCIN/POLYMYXN B/GRAMICIDIN	DROPS
		OFLOXACIN	DROPS
		POLYMYXIN B SULFATE/TMP	DROPS
		SULFACETAMIDE SODIUM	DROPS
		TOBRAMYCIN SULFATE	DROPS
		TOBRAMYCIN SULFATE	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 September 24, 2012

System	Class	Preferred	
Ophthalmic	Anti-Inflammatory Drugs	DEXAMETHASONE	DROPS SUSP
		DEXAMETHASONE SOD PHOSPHATE	DROPS
		DICLOFENAC SODIUM	DROPS
		FLUOROMETHOLONE	DROPS SUSP ***
		FLUOROMETHOLONE	OINT. (G)
		FLURBIPROFEN SODIUM	DROPS
		KETOROLAC TROMETHAMINE	DROPS
		LOTEPREDNOL ETABONATE	DROPS SUSP ***
	PREDNISOLONE ACETATE	DROPS SUSP ***	
Ophthalmic	Glaucoma	APRACLONIDINE HCL	DROPS
		BETAXOLOL HCL	DROPS
		BRIMONIDINE TARTRATE	DROPS ***
		BRINZOLAMIDE	DROPS SUSP
		CARTEOLOL HCL	DROPS
		DORZOLAMIDE HCL/TIMOLOL MALEAT	DROPS
		PILOCARPINE HCL	DROPS
		PILOCARPINE HCL	GEL (GRAM)
		TIMOLOL MALEATE	DROPS
	TRAVOPROST(TRAVATAN Z®)	DROPS	
Otic	Antibiotic	CIPROFLOXACIN HCL/DEXAMETH(CIPRODEX®)	DROPS SUSP
		NEOMY SULF/COLIST SUL/HC/THONZ	DROPS SUSP
		OFLOXACIN	DROPS
Psychiatric	ADHD	AMPHET ASP/AMPHET/D-AMPHET **	TABLET
		DEXMETHYLPHENIDATE HCL **	TABLET
		DEXTROAMPHETAMINE SULFATE **	TABLET
		LISDEXAMFETAMINE DIMESYLATE(VYVANSE®) **	CAPSULE
		METHYLPHENIDATE HCL	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 September 24, 2012

System	Class	Preferred	
Pulmonary	Anticholinergic Inhalers	IPRATROPIUM BROMIDE	HFA AER AD
		IPRATROPIUM BROMIDE	SOLUTION
		IPRATROPIUM/ALBUTEROL SULFATE	AER W/ADAP
		IPRATROPIUM/ALBUTEROL SULFATE	AMPUL-NEB
		TIOTROPIUM BROMIDE(SPIRIVA®)	CAP W/DEV
Pulmonary	Asthma Controllers	BECLOMETHASONE DIPROPIONATE(QVAR®)	AER W/ADAP
		FLUTICASONE PROPIONATE(FLOVENT DISKUS®)	DISK W/DEV
		FLUTICASONE PROPIONATE(FLOVENT HFA®)	AER W/ADAP
		FORMOTEROL FUMARATE	CAP W/DEV
		MOMETASONE FUROATE	AER POW BA
		MONTELUKAST SODIUM *	GRAN PACK
		MONTELUKAST SODIUM *	TAB CHEW
		MONTELUKAST SODIUM *	TABLET
		SALMETEROL XINAFOATE	DISK W/DEV
ZAFIRLUKAST	TABLET		
Pulmonary	Asthma Rescue	ALBUTEROL SULFATE	SOLUTION
		ALBUTEROL SULFATE	VIAL-NEB
		PIRBUTEROL ACETATE	AER BR.ACT
		PROAIR HFA® - BRAND ONLY	HFA AER AD
		PROVENTIL HFA® - BRAND ONLY	HFA AER AD
Pulmonary	PAH	BOSENTAN(TRACLEER®) *	TABLET
		SILDENAFIL CITRATE *	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 September 24, 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
		QUETIAPINE FUMARATE *	TABLET
		RISPERIDONE	SOLUTION
		RISPERIDONE	TAB RAPDIS
		RISPERIDONE	TABLET
		ZIPRASIDONE HCL	CAPSULE

* 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 ~~August 20~~September 24, 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

9-26-12 (T)

Erythropoiesis Stimulating Agents (ESAs)

Goal(s):

- Cover ESAs according to OHP guidelines¹ and current medical literature.
- Cover preferred products when feasible.

Length of Authorization:

- 8 weeks initially, then up to 12 months
- Quantity limit of 30 day per dispense

Requires PA:

- All ESAs require PA for clinical appropriateness.

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is this an OHP covered diagnosis?	Yes: Go to #3	No: Pass to RPH; Deny (not covered by the OHP).
3. Is this continuation therapy?	Yes: Go to #12	No: Go to #4
4. Is the requested product preferred?	Yes: Go to #6	No: Go to #5
5. Will the Prescriber change to a preferred product?	Yes: Inform provider of covered alternatives in class. Go to #6	No: Go to #6
6. Is the diagnosis anemia due to chronic renal failure ² or chemotherapy ^{3,4} ?	Yes: Go to #7	No: Go to #8
7. Is Hb < 10g/dl or Hct < 30% AND Transferrin saturation >20% and/or ferritin >100ng/ml?	Yes: Approve for 8 weeks with additional approval based upon adequate response.	No: Pass to RPH; Deny (not medically appropriate).
8. Is the diagnosis anemia due to HIV ⁵ ?	Yes: Go to #9	No: Go to #10
9. Is the Hb < 10g/dL or Hct < 30% AND Transferrin saturation > 20% AND Endogenous erythropoietin < 500 iu/L AND If on Zidovudine is dose < 4200mg/week?	Yes: Approve for length of Rx or 12 months, whichever is less.	No: Pass to RPH; Deny (not medically appropriate).

CRITERIA RE-WRITTEN

Approval Criteria		
10. Is the diagnosis anemia due to ribavirin treatment ⁶ ?	Yes: Go to #11	No: Pass to RPh; Deny, (not medically appropriate).
11. Is the Hb < 10g/dL or Hct < 30% AND Is the transferrin saturation >20% and/or ferritin >100ng/ml AND Has the dose of ribavirin been reduced by 200mg/day and anemia persisted > 2 weeks?	Yes: Approve up to the length of ribavirin treatment.	No: Pass to RPh; Deny (not medically appropriate).
12. Has the patient responded to initial therapy?	Yes: Approve for length of Rx or 12 months, whichever is less.	No: Pass to RPh; Deny (not medically appropriate).

References:

1. Oregon Health Policy and Research Current Prioritized List of Health Services. Available at: <http://cms.oregon.gov/oha/OHPR/pages/herc/current-prioritized-list.aspx>. Accessed September 12, 2012.
2. National Kidney Foundation. NKF KDOQI Guidelines. *NKF KDOQI Guidelines*. 2006. Available at: http://www.kidney.org/professionals/KDOQI/guidelines_anemia/index.htm. Accessed May 25, 2012.
3. Rizzo JD, Brouwers M, Hurley P, et al. American Society of Clinical Oncology/American Society of Hematology Clinical Practice Guideline Update on the Use of Epoetin and Darbepoetin in Adult Patients With Cancer. *JCO*. 2010;28(33):4996–5010. Available at: <http://jco.ascopubs.org.liboff.ohsu.edu/content/28/33/4996>. Accessed May 1, 2012.
4. Rizzo JD, Brouwers M, Hurley P, et al. American Society of Hematology/American Society of Clinical Oncology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer. *Blood*. 2010;116(20):4045–4059.
5. Volberding PA, Levine AM, Dieterich D, et al. Anemia in HIV Infection: Clinical Impact and Evidence-Based Management Strategies. *Clin Infect Dis*. 2004;38(10):1454–1463. Available at: <http://cid.oxfordjournals.org/content/38/10/1454>. Accessed May 8, 2012.
6. Recombinant Erythropoietin Criteria for Use for Hepatitis C Treatment-Related Anemia. VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel. April 2007

P&T / DUR Board Action: 6/28/12(KK); 2/23/12, 09/16/2010 (DO)

Revision(s): 9/24/12, 5/14/12

Initiated: 1/1/11

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 request from or in consultation with a pulmonologist?	Yes: Go to #5.	No: Pass to RPH; Deny (medical appropriateness)
5. Does the patient have a baseline FEV1% predicted between 40-90%?	Yes: Go to #6.	No: Pass to RPH; Deny (medical appropriateness)
6. Is the patient on ALL or has had an adequate trial of the following medications below: - Dornase alfa (Pulmozyme®) AND - Hypertonic saline (Hyper-Sal®) AND - Inhaled or oral antibiotics (if appropriate)	Yes: Go to #7	No: Pass to RPH; Deny (medical appropriateness)
7. Is the prescription for ivacaftor 150mg twice daily, once daily or twice-a-week?	Yes: Approve for 3 months.	No: Pass to RPH; Deny (medical appropriateness)

CRITERIA RE-WRITTEN

Renewal Criteria		
1. Is this the first time the patient is requesting a renewal?	Yes: Go to #2.	No: Pass to RPH; Deny (medical appropriateness)
2. Does the patient have documented response to therapy, as indicated by an increase in FEV1 by $\geq 5\%$ after 3 months of therapy?	Yes: Go to #3.	No: Pass to RPH; Deny (medical appropriateness)
3. Has the patient been compliant with therapy, as determined by refill claims history?	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 3 months.	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.

P&T / DUR Action: 6/28/12 (KS), 4/26/12 (MH/KS)
Revision(s): 9/24/12
Initiated: 7/23/12