Background

COX Caren S

From: sonia.gates@advancepcs.com
Sent: Sunday, December 07, 2003 6:55 PM
To: sonia.gates@advancepcs.com
Subject: New Drug - Raptiva

Raptiva - Advisor Update.doc (...

Hello-

Recently, the FDA approved the drug Raptiva, an injectable product for the treatment of moderate-to-severe plaque psoriasis. This drug is indicated for adults age 18 and older who are candidates for systemic therapy or phototherapy. Raptiva will be available in mid-December and the costs are estimated to range from $15,000 - $18,000 per member per year. I have attached AdvancePCS Advisor Update that you should have received last week by fax for your reference.

Most biotech drugs, such as Raptiva, are often associated with rare conditions. However, Raptiva is one of the first injectables offered for a common chronic condition with the potential to be used for hundreds of thousands of individuals. It is expected that out of the 4.5 million Americans with psoriasis, that about 500,000 are potential candidates for this therapy.

The AdvancePCS' specialty pharmacy can now provide Raptiva to patients with plaque psoriasis. Since this drug is subject to limited distribution, effective January 1, 2004, any prescription submitted through the retail or mail benefit will be directed to AdvancePCS' specialty pharmacy for fulfillment. This will ensure that our clients get the full benefit of the management services our specialty pharmacy offers.

If you would like more stringent controls surrounding Raptiva, prior authorization can be implemented on this drug. Please let me know if you would like to implement prior authorization and I will forward you the necessary forms.

(See attached file Raptiva - Advisor Update.doc)

Thank you

Sonia
Sonia Gates
AdvancePCS, Clinical Manager
(480) 627-0646
Sonia.Gates@AdvancePCS.com

Utilization Management

Implementation Form (RxClaim)

AdvancePCS

Client Detail

Client Name: Multnomah County					**State** (eg. AZ, TX): OR
Client Contact: Caren Cox					
CM/CD/: Sonia Gates					
Client Specialist: Brian Hendricks					
Check all that apply:					
☐ New Plan Sponsor	☒ Employer	☐ Taft-Hartley	☐ Govt	☐ BCBS	☐ AdvanceRx.com™
☒ Existing Plan Sponsor	☐ TPA	☐ Comm HP	☐ Govt Funded HP		☐ Other Mail Service
Effective Date:		**Establish effective date with PA Manager.** *(Standard lead time is maximum 60 days from receipt of signed documentation.)*			
Carrier(s): 3040		**Member Services provided by:** ☒ AdvancePCS ☐ Client Phone number:			
If this does not apply to ALL Accounts, Groups and Plans, please specify who it should apply to:					
Total Members:	5000	Please provide. Used to project call volume in PA pkg.			

Program Options & Pricing *(Check all that apply)*

See UM Fee Schedule for current pricing

☒	Prior Authorization	Attach PA product sheet and criteria (p.2)	Provide approved price: $ 12
☐	Drug Limitations (QVT/MDL)	Attach Drug Limitations product sheet (p.4-5)	No Charge (Client's PA fee applies to post-limit PA requests)
☐	Step Therapy	Attach Step Therapy product sheet (p.6-8)	No Charge (Client's PA fee applies to post-Step PA requests)
☐	Prescription Claim Appeals	Attach Appeals product sheet (p.9)	$____/Benefit Reconsideration Medical Necessity: see Addendum

Client Signature

I have reviewed the attached documentation and conclude all information to be correct. (All signatures required)

Client Signature Multnomah County-Client Date 12-31-03

Print Name CAREN COX

CM/CD/AM Signature _____ Date _____

Print Name _____

Attn: Clinical Managers:

Forward all signed UM Implementation forms and all signed PA criteria to:

UM Receiving
Mail Code 512, 2nd Floor (PA Area)
Fax 469-524-7141
UMForm@Advancepcs.com

Utilization Management

AdvancePCS

Prior Authorization Attach to Implementation Form

AdvancePCS Recommended † (Signed criteria required)

Action	Drug Class	Drugs in Class
Tier 1 -- Low member impact; low savings potential *(Tier 1 drugs are No Charge)*		
☐Add ☐Delete	Anabolic Steroids	Anadrol-50, Oxandrin, Winstrol
☐Add ☐Delete	Gaucher Disease	Ceredase, Cerezyme, Zavesca
☐Add ☐Delete	Growth Hormones	Genotropin, Geref, Humatrope, Norditropin, Nutropin, Nutropin AQ, Nutropin Depot, Protropin, Serostim,Saizen
☐Add ☐Delete	Interferons (Select)	Copegus, Infergen, Intron-A, Pegasys, Peg-Intron, Rebetol, Rebetron, Roferon A
Tier 2 – More clinically aggressive; higher member impact; high potential for misuse or abuse; higher savings potential		
☐Add ☐Delete	Antiobesity	benzphetamine, diethylpropion, Meridia, phendimetrazine, phentermine, Xenical
☐Add ☐Delete	Antiemetics	Emend
☐Add ☐Delete	Diabetic Ulcer	Regranex
☐Add ☐Delete	Erectile Dysfunction	Caverject, Cialis, Edex, Levitra, Muse, Viagra
☐Add ☐Delete	MS Drugs	Avonex, Betaseron, Copaxone, Novantrone, Rebif
☐Add ☐Delete	ADHD/Narcolepsy Agents (Age ≥19)	Adderall, Adderall XR, Concerta, Cylert, Desoxyn, Dexedrine, Dextrostat, Focalin, Metadate CD, Metadate ER Provigil, Ritalin, Ritalin LA, Strattera
☐Add ☐Delete	AIDs Therapy	Fuzeon
☐Add ☐Delete	Alzheimer's	Aricept, Cognex, Exelon, Namenda, Reminyl
☐Add ☐Delete	Anemia Agents	Aranesp, Epogen, Procrit
☐Add ☐Delete	Arthritis	Arava, Enbrel, Humira, Kineret, Remicade
☐Add ☐Delete	Asthma	Xolair
☐Add ☐Delete	Botulinum Toxin	Botox, Myobloc
☐Add ☐Delete	Irritable Bowel Syn	Lotronex, Zelnorm
☐Add ☐Delete	Oral Acne Agents	Accutane, Sotret
☐Add ☐Delete	Oral Antifungal	Diflucan (all strengths except 150mg), Lamisil, Sporanox
☐Add ☐Delete	Osteoporosis	Forteo
☐Add ☐Delete	Psoriasis	Soriatane
☐Add ☐Delete	Topical Acne Agents (Age ≥25*)	Altinac, Avita, Differin, Retin-A, Tazorac *(*PA for all ages on Tazorac)*

Prior Authorization (Client Specific or Custom):

*****Add Raptiva*****

Pre-Implementation Letters (Mailing charge Add'l) (Mail no sooner than 10 business days prior to Eff. Date)

☐Member ☐Provider ☐Both ☒N/A	Produced by: ☐ AdvancePCS or ☐Client (attach copy to this form)

Prior Authorization Appeal Process **(Required for every plan – PA cannot go live without)**

Processed by: ☐AdvancePCS (complete Prescription Claim Appeals page)
☒Client ☐Other Contracted Agent -- Provide the following information:

Appeals Contact: Caren Cox

Method of Contact: ☐Fax _____ ☒ Letter

Contact Allowed From: ☒Provider ☒Member Required Appeals Info:

PA Msg: Prior Authorization Required-MD Call 1-8xx-xxx-xxxx	Post-Limit Msg: Prior Authorization Required – limit exceeded-MD call 1-8xx-xxx-xxxx

AdvancePCS

PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**Raptiva**
(Generic)	**(efalizumab)**

PA Status: Client Requested/AdvancePCS Recommended
PA Type: Initial PA

FDA-APPROVED INDICATION

Raptiva (efalizumab) is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

PA CRITERIA FOR APPROVAL

1.	Is the patient ≥ 18 years of age?	Yes	No
2.	Does the patient have a diagnosis of chronic moderate to severe plaque psoriasis?	Yes	No
3.	Is the patient a candidate for systemic therapy or phototherapy?	Yes	No
4.	Does the patent have a clinically important infection?	Yes	No
5.	Will the physician monitor platelet levels regularly during treatment with Raptiva?	Yes	No
6.	Is the patient currently receiving other immunosuppressive therapy or phototherapy? [Tech Only: If the answer to this question is no, then no further questions are required.]	Yes	No
7.	Will the immunosuppressive therapy or phototherapy be discontinued?	Yes	No

Guidelines for Approval				
Duration of Approval		**12 months**		
Set 1		**Set 2**		
Yes to Question(s)	**No to question(s)**	**Yes to Question(s)**	**No to question(s)**	
1	4	1	4	
2	6	2		
3		3		
5		5		
		6		
		7		

BLACK BOX WARNINGS
None

RATIONALE

The intent of the criteria is to ensure that patients follow selection elements noted in labeling. Raptiva is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Raptiva is an immunosuppressive agent and has the potential to increase the risk of infection and reactivate latent, chronic infections. Raptiva should not be administered to patients with clinically important infections. Assessment of platelet counts is recommended upon initiating and periodically while receiving Raptiva treatment. It is recommended that platelet count assessments be more frequent when initiating therapy and may decrease in frequency with continued treatment. The safety and efficacy of Raptiva in combination with other immunosuppressive agents or phototherapy have not been evaluated. Patients receiving other immunosuppressive agents should not receive concurrent therapy with Raptiva because of the possibility of increased risk of infections and malignancies.

ADDITIONAL INFORMATION

Raptiva (efalizumab) is an immunosuppressive recombinant humanized IgG1 kappa isotype monoclonal antibody that binds to human 6CD11a. RAPTIVA binds to CD11a, the α subunit of leukocyte function antigen-1 (LFA-1), which is expressed on all leukocytes, and decreases cell surface expression of CD11a. RAPTIVA inhibits the binding of LFA-1 to intercellular adhesion molecule-1 (ICAM-1), thereby inhibiting the adhesion of leukocytes to other cell types. Interaction between LFA-1 and ICAM-1 contributes to the initiation and maintenance of multiple processes, including activation of T lymphocytes, adhesion of T lymphocytes to endothelial cells, and migration of T lymphocytes to sites of inflammation including psoriatic skin.

Dosage and Administration:
The recommended dose of RAPTIVA is a single 0.7 mg/kg SC conditioning dose followed by weekly SC doses of 1 mg/kg (maximum single dose not to exceed a total of 200 mg). RAPTIVA is intended for use under the guidance and supervision of a physician. If it is determined to be appropriate, patients may self-inject RAPTIVA after proper training in the preparation and injection technique and with medical follow-up.

CONTRAINDICATIONS/WARNINGS/PRECAUTIONS

Warnings:

Serious Infections
Raptiva is an immunosuppressive agent and has the potential to increase the risk of infection and reactivate latent, chronic infections. Raptiva should not be administered to patients with clinically important infections. Caution should be exercised when considering the use of Raptiva in patients with a chronic infection or history of recurrent infections. If a patient develops a serious infection, Raptiva should be discontinued. Serious infections requiring hospitalization included cellulitis, pneumonia, abscess, sepsis, bronchitis, gastroenteritis, aseptic meningitis, Legionnaire's disease, and vertebral osteomyelitis.

Malignancies
Raptiva is an immunosuppressive agent. Many immunosuppressive agents have the potential to increase the risk of malignancy. The role of Raptiva in the development of malignancies is not known. Caution should be exercised when considering the use of RAPTIVA in patients at high risk for malignancy or with a history of malignancy. If a patient develops a malignancy, RAPTIVA should be discontinued

Thrombocytopenia
Platelet counts at or below 52,000 cells per µL were observed in 8 (0.3%) Raptiva-treated patients during clinical trials compared with none among the placebo-treated patients. Assessment of platelet counts is recommended during treatment with Raptiva. Raptiva should be discontinued if thrombocytopenia develops.

Psoriasis Worsening and Variants
Worsening of psoriasis can occur during or after discontinuation of Raptiva. In some patients these events took the form of psoriatic erythroderma or pustular psoriasis. Some patients required hospitalization and alternative antipsoriatic therapy to manage the psoriasis worsening. Patients, including those not responding to Raptiva treatment, should be closely observed following discontinuation of Raptiva, and appropriate psoriasis treatment instituted as necessary.

Precautions:

Immunosuppression
The safety and efficacy of Raptiva in combination with other immunosuppressive agents or phototherapy have not been evaluated. Patients receiving other immunosuppressive agents should not receive concurrent therapy with Raptiva because of the possibility of increased risk of infections and malignancies.

Immunizations
The safety and efficacy of vaccines, administered to patients being treated with Raptiva have not been studied. Acellular, live and live-attenuated vaccines should not be administered during Raptiva treatment.

First Dose Reactions
First dose reactions including headache, fever, nausea, and vomiting are associated with Raptiva treatment and are dose-level related in incidence and severity. Therefore, a conditioning dose of 0.7 mg/kg is recommended to reduce the incidence and severity of reactions associated with initial dosing.

Laboratory Tests
Assessment of platelet counts is recommended upon initiating and periodically while receiving Raptiva treatment. It is recommended that assessments be more frequent when initiating therapy (e.g., monthly) and may decrease in frequency with continued treatment (e.g., every 3 months).

Pregnancy Category C
Since the effects of RAPTIVA on pregnant women and fetal development, including immune system development are not known, healthcare providers are encouraged to enroll patients who become pregnant while taking Raptiva (or within 6 weeks of discontinuing Raptiva) in the Raptiva Pregnancy Registry.

Pediatric Use
The safety and efficacy of RAPTIVA in pediatric patients have not been studied.

Geriatric Use
Because the incidence of infections is higher in the elderly population, in general, caution should be used in treating the elderly.

REFERENCES

1. Raptiva product information. Genentech, Inc. October 2003.

Written by:	Jacque Griffith, Pharm.D.
Date Written:	10/2003
Revised:	
Reviewed:	CRC ##/2000
	External Review:

This Health Plan hereby accepts and adopts as their own the criteria for use with Prior Authorization, as administered by AdvancePCS.

Signature

12-31-03
Date

Multnomah County
Health Plan