

POLICY AND PROCEDURE

DEPARTMENT: Medical Affairs/Pharmacy	REFERENCE NUMBER: GA.PHAR.15
EFFECTIVE DATE: 03/2010	POLICY NAME: SPECIALTY DRUG CLASSIFICATION
REVIEWED/REVISED DATE: 06/17, 04/18, 06/18, 02/19, 04/19, 04/2020	RETIRED DATE: N/A
PRODUCT TYPE: Medicaid	PAGE: 1 of 5

SCOPE:

Peach State Health Plan Pharmacy Department

PURPOSE:

To ensure that Peach State Health Plan has clearly defined criteria for classification of drugs as part of the specialty drug category, classification of a specialty drug as urgent/expedited or standard, requirements for prior authorization turnaround time for drugs in the designated category, and definition of a valid request.

POLICY:

Therapy classes will be evaluated by the Peach State P&T Committee to determine if the drugs within a class meet criteria for classification as a specialty drug. New drug arrivals to the market will be evaluated by the P&T committee within 180 days of market introduction only if they do not fall into one of the existing therapy classes. New drug arrivals that do fall into one of the already existing therapy classes will be considered to follow the same process as the other drugs available in the class. Drugs within a specialty class will be processed according to the path and timeframe of a medical approval. Expedited requests will be handled according to the NCQA guidelines for expedited medical requests.

PROCEDURE:

Specialty Drugs are defined as specialized therapies developed for chronic, complex illnesses and:

- may have special handling, storage, shipping requirements
- may require nursing services or special programs to support patient compliance
- require disease-specific treatment programs
- may have limited distribution requirements
- may be injections, infusions, or oral products
- are high cost, typically > \$500 per treatment episode
- are not typically stocked in a retail pharmacy
- are not typically first line agents
- may require increased monitoring due to safety concerns
- may be subject to inappropriate administration
- may be dispensed in a physician's office or an outpatient infusion center
- are such that the immediate administration of the drug will not be necessary to prevent serious jeopardy to the life or health of the patient

Some of the conditions treated by specialty drugs and/or existing classes of specialty drugs that would be considered standard requests include the following:

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- Allergic Asthma
- Cancer
- Crohn's Disease
- Cystic Fibrosis
- Growth Hormone and Related Disorders
- Anemia (only certain therapies that are regularly dispensed through specialty distribution networks)
- Hemophilia, Von Willebrand Disease and Related Bleeding Disorders
- Hepatitis C
- Hereditary Angioedema
- HIV/AIDS (only certain therapies that are regularly dispensed through specialty distribution networks)
- Hormonal Therapies (only certain therapies that are regularly dispensed through specialty distribution networks)
- Immune Deficiencies and Related Disorders
- Lysosomal Storage Disorders
- Macular Degeneration
- Multiple Sclerosis
- Neutropenia
- Osteoarthritis
- Osteoporosis
- Psoriasis and Psoriatic Arthritis
- Pulmonary Arterial Hypertension
- Pulmonary Disease
- Renal Disease
- Respiratory Syncytial Virus
- Rheumatoid Arthritis
- Growth Hormone Deficiency
- Precocious Puberty
- Endometriosis

** This list may not be all-inclusive and is subject to change if new drugs are introduced into the market (see above policy statement about P&T review of new drugs).

Prior authorization requests for drugs meeting the criteria above will be considered standard and processed in accordance with the stricter of NCQA standard turnaround time requirements (currently 15 calendar days) or the Department of Community Health (DCH) Contract requirements for nonurgent preservice decisions (currently 3 business days as defined by the DCH Contract). However, if prior authorization requests for drugs are indicated by the provider

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as “urgent” or “expedited” but does not meet the above criteria, written notification will be sent to the provider informing the authorization request will be processed as standard.

Some of the conditions treated by specialty drugs that would be considered urgent/expedited requests include the following:

- Clotting disorders treated by Low Molecular Weight Heparins
- Prevention of organ rejection with Immunosuppressants

** This list may not be all-inclusive and is subject to change if new drugs are introduced into the market (see above policy statement about P&T review of new drugs).

Prior authorization requests for drugs meeting the criteria above will be considered urgent/expedited and processed in accordance with the stricter of NCQA urgent turnaround time requirements (currently 72 hours) or DCH requirements for urgent preservice decisions (currently 24 to 72 hours from the receipt of the request).

A Prior Authorization request must include, at minimum, the patient name and Medicaid ID # or the patient name and date of birth, the drug name, the patient’s diagnosis for which the drug is being used, and prescriber’s name and phone number. If any of this information is missing, the request will not be considered a valid prior authorization request, and will not be processed until all necessary information is received.

If a designated vendor for Peach State (Envolve Pharmacy Solutions or Acaria) receives a request that does not include the Medicaid ID #, the request will not be considered valid until insurance has been verified.

REFERENCES:

DCH Contract with Peach State Health Plan

ATTACHMENTS: N/A**DEFINITIONS:** N/A

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REVISION LOG	DATE
Added "New drug arrivals to the market will be evaluated by the P&T committee within 180 days of market introduction only if they do not fall into one of the existing therapy classes. New drug arrivals that do fall into one of the already existing therapy classes will be considered to follow the same process as the other drugs available in the class." to POLICY.	03/2010
Removed drug category Hematopoietics, and added Anemia, Hormonal Therapies and Neutropenia to PROCEDURE.	03/2010
Added "if new drugs are introduced into the market (see above policy statement about P&T review of new drugs)" to PROCEDURE.	03/2010
Added "classification of a specialty drug as urgent/expedited or standard" and "definition of a valid request" to PURPOSE.	06/2010
Added clarification regarding what is considered a standard request to PROCEDURE.	06/2010
Added a section regarding what is considered urgent/expedited request and turnaround time for urgent/expedited requests to PROCEDURE.	06/2010
Added explanation of what is considered a valid request to PROCEDURE.	06/2010
Replaced all Carecentrix instances with Univita	06/2011
Removed Peach State Health Plan Chief Medical Director from SCOPE.	06/2011
Updated DEPARTMENT header by removing Medical Management and adding Medical Affairs	06/2011
Annual review. Updated references from NCQA 2010 MCO Standards and Guidelines to NCQA 2012 MCO Standards and Guidelines.	06/2012
Annual review. Updated references from NCQA 2012 MCO Standards and Guidelines to NCQA 2013 MCO Standards and Guidelines.	06/2013
Annual review. Replaced all Caremark references to Acaria. Updated references from NCQA 2013 MCO Standards and Guidelines to NCQA 2014 MCO Standards and Guidelines	06/2014
Added sentence to notify provider when criteria does not meet an urgent/expedited request.	07/14
Annual review. Updated references from NCQA 2014 MCO Standards and Guidelines to NCQA 2015 MCO Standards and Guidelines.	6/2015
Annual review. Updated references from NCQA 2014 MCO Standards and Guidelines to NCQA 2016 MCO Standards and Guidelines. Updated designated vendor from US Script to Envolve Pharmacy Solutions and removed Univita.	6/2016
Annual review. Added that TAT will be 3 business days beginning 7/1/2017 due to the new contract.	4/2017
Annual review. No changes made.	6/2017

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Annual review. No changes made.	4/2018
Annual review. No changes made.	6/2018
Changed current Georgia policy templates to corporate standard templates for standard operating policy/procedures criteria to meet corporate compliance. Changes/revisions included; new formatting, font size, use of standard policy language for each section of policy, and rearranged order of certain steps in criteria and sections.	2/2019
Annual review. No changes made.	4/2019
Annual review. Update decision time frames for nonurgent and urgent prior authorization requests based on NCQA or DCH.	4/2020

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.