SELF-ADMINISTERED MEDICATIONS

Policy Number: 2018D0073B
Effective Date: December 1, 2018

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Related Commercial Policies
- Hereditary Angioedema (HAE), Treatment and Prophylaxis
- Ilumya™ (Tildrakizumab-Asmn)
- Repository Corticotropin Injection (H.P. Acthar Gel®)
- Stelara® (Ustekinumab)

INSTRUCTIONS FOR USE

This Drug Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Drug Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Drug Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Drug Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy. Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. See the Policy and Procedure addressing the treatment of serious rare diseases.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.
COVERAGE RATIONALE

Self-Administered medications are excluded from standard medical benefit plans. We will determine if a medication is self-administered based on the following:

I. Medication is not typically administered or directly supervised by a qualified provider or licensed/certified health professional in an outpatient setting; and

II. Medication does not require continuous or periodic monitoring immediately before, during, or after administration by a qualified provider or licensed/certified health professional in an outpatient setting; and

III. Route of administration (e.g., oral, topical, rectal, subcutaneous or some intramuscular injections); and

IV. Dosage form (e.g., prefilled syringe, auto-injector, tablet, capsule, suppository); and

V. Acuity of condition (e.g., chronic disease); and

VI. Frequency of administration; and

VII. The medication is not specifically allowed under the medical benefit; and

VIII. Standards of medical practice allowing for self-administration (e.g., self-infused hemophilia factor); and

IX. Evaluation of any established medical literature or compendia including but not limited to:
   A. FDA approved prescribing information
   B. Manufacturer provided medical literature
   C. Peer reviewed medical literature
   D. Evidence-based practice guidelines
   E. Self-administration utilization statistics
   F. Compendia (e.g., IBM Micromedex® DRUGDEX®, Clinical Pharmacology)

BACKGROUND

Medications administered by the patient that do not require direct supervision by a qualified provider or licensed/certified health professional are considered self-administered drugs and not covered under the medical benefit.

APPLICABLE CODES

Refer to the Self-Administered Medications List for applicable HCPCS codes for medications UnitedHealthcare has determined to be “self-administered” based upon the review of evidence stated within the Coverage Rationale. Any applicable clinician administered dosage formulations (e.g., intravenous infusion) of the drugs on the Self-Administered Medications List may be covered under the medical benefit.

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<thead>
<tr>
<th>Revenue Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0637</td>
<td>Self-administered drugs (use this revenue code for self-administered drugs not requiring detailed coding)</td>
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CENTERS FOR MEDICARE AND MEDICAID SERVICES

Medicare does not have a National Coverage Determination (NCD) specific to the self-administration of drugs. Local Coverage Determinations (LCDs)/ Local Coverage Articles (LCAs) exist; see the LCAs for Self-Administered Drugs - Process To Determine Which Drugs Are Usually Self-Administered by the Patient, Self-Administered Drug Exclusion List and Biologicals Excluded from Coverage - Medical Policy Article (R7), Self-Administered Drug Exclusion List (SAD List) and Self-administered drug (SAD) list revision to the Part A and Part B article.

In general, Medicare provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, Section 50.2 - Determining Self-Administration of Drug or Biological. (Accessed April 27, 2018)

REFERENCES

1. IBM Micromedex® DRUGDEX® (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com/


4. Drugs@FDA: FDA Approved Drug Products
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<th>Date</th>
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<td>07/01/2018</td>
<td>New policy 2018D0073A. Approved by National Pharmacy &amp; Therapeutics Committee on 06/20/2018.</td>
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