SELF-ADMINISTERED MEDICATIONS

Policy Number: 2019D0073C  Effective Date: March 1, 2019

Table of Contents  Page
COVERAGE RATIONALE .............................................. 1
BACKGROUND ............................................................. 1
APPLICABLE CODES ............................................... 1
BENEFIT CONSIDERATIONS ...................................... 2
CENTERS FOR MEDICARE AND MEDICAID SERVICES ... 2
REFERENCES ............................................................... 2
POLICY HISTORY/REVISION INFORMATION ............... 2
INSTRUCTIONS FOR USE ........................................... 2

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

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 Micromedx® 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.

<table>
<thead>
<tr>
<th>Revenue Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0637</td>
<td>Self-administered drugs (use this revenue code for self-administered drugs not requiring detailed coding)</td>
</tr>
</tbody>
</table>
BENEFIT CONSIDERATIONS

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.

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.

POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/01/2019</td>
<td>Reorganized policy template; simplified and relocated Instructions for Use and Benefit Considerations section. Archived previous policy version 2018D0073B.</td>
</tr>
<tr>
<td>07/01/2018</td>
<td>New policy 2018D0073A. Approved by National Pharmacy &amp; Therapeutics Committee on 06/20/2018.</td>
</tr>
</tbody>
</table>

INSTRUCTIONS FOR USE

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Drug Policies 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.