L-DOPA (NCD 160.17)

Guideline Number: MPG190.04

Overview
Levodopa is used in the treatment of Parkinson's disease. Parkinson's disease is believed to be caused by low levels of dopamine in certain parts of the brain. When levodopa is taken orally, it crosses into the brain through the "blood-brain barrier." Once it crosses, it is converted to dopamine.

Guidelines
Part A Payment for L-Dopa and Associated Inpatient Hospital Services
A hospital stay and related ancillary services for the administration of L-Dopa are covered if medically required for this purpose. Whether a drug represents an allowable inpatient hospital cost during such stay depends on whether it meets the definition of a drug in §1861(t) of the Act; i.e., on its inclusion in the compendia named in the Act or approval by the hospital's pharmacy and drug therapeutics (P&amp;DT) or equivalent committee. (Levodopa (L-Dopa) has been favorably evaluated for the treatment of Parkinsonism by A.M.A. Drug Evaluations, First Edition 1971, the replacement compendia for "New Drugs.")

Inpatient hospital services are frequently not required in many cases when L-Dopa therapy is initiated. Therefore, determine the medical need for inpatient hospital services on the basis of medical facts in the individual case. It is not necessary to hospitalize the typical, well-functioning, ambulatory Parkinsonian patient who has no concurrent disease at the start of L-Dopa treatment. It is reasonable to provide inpatient hospital services for Parkinsonian patients with concurrent diseases, particularly of the cardiovascular, gastrointestinal, and neuropsychiatric systems. Although many patients require hospitalization for a period of under 2 weeks, a 4-week period of inpatient care is not unreasonable.

Laboratory Tests in Connection with the Administration of L-Dopa
The tests medically warranted in connection with the achievement of optimal dosage and the control of the side effects of L-Dopa include a complete blood count, liver function tests such as SGOT, SGPT, and/or alkaline phosphatase, BUN or creatinine and urinalysis, blood sugar, and electrocardiogram.

Whether or not the patient is hospitalized, laboratory tests in certain cases are reasonable at weekly intervals although some physicians prefer to perform the tests much less frequently.

Physical Therapy Furnished in Connection with Administration of L-Dopa
Where, following administration of the drug, the patient experiences a reduction of rigidity which permits the reestablishment of a restorative goal for him/her, physical therapy services required to enable him/her to achieve this goal are payable provided they require the skills of a qualified physical therapist and are furnished by or under the supervision of such a therapist. However, once the individual's restoration potential has been achieved, the services required to maintain him/her at this level do not generally require the skills of a qualified physical therapist. In such situations, the role of the therapist is to evaluate the patient's needs in consultation with his/her physician and design a program of exercise appropriate to the capacity and tolerance of the patient and treatment objectives of the physician, leaving to others the actual carrying out of the program. While the evaluative services rendered by a...
qualified physical therapist are payable as physical therapy, services furnished by others in connection with the carrying out of the maintenance program established by the therapist are not.

**Part A Reimbursement for L-Dopa Therapy in Skilled Nursing Facilities (SNFs)**
Initiation of L-Dopa therapy can be appropriately carried out in the SNF setting, applying the same guidelines used for initiation of L-Dopa therapy in the hospital, including the types of patients who should be covered for inpatient services, the role of physical therapy, and the use of laboratory tests. (See subsection A.)

Where inpatient care is required and L-Dopa therapy is initiated in the SNF, limit the stay to a maximum of 4 weeks; but in many cases the need may be no longer than 1 or 2 weeks, depending upon the patient's condition. However, where L-Dopa therapy is begun in the hospital and the patient is transferred to an SNF for continuation of the therapy, a combined length of stay in hospital and SNF of no longer than 4 weeks is reasonable (i.e., 1 week hospital stay followed by 3 weeks SNF stay; or 2 weeks hospital stay followed by 2 weeks SNF stay; etc.). Medical need must be demonstrated in cases where the combined length of stay in hospital and SNF is longer than 4 weeks. The choice of hospital or SNF, and the decision regarding the relative length of time spent in each, should be left to the medical judgment of the treating physician.

**L-Dopa Coverage Under Part B**
Part B reimbursement may not be made for the drug L-Dopa since it is a self-administrable drug. However, physician services rendered in connection with its administration and control of its side effects are covered if determined to be reasonable and necessary. Initiation of L-Dopa therapy on an outpatient basis is possible in most cases. Visit frequency ranging from every week to every 2 or 3 months is acceptable. However, after half a year of therapy, visits more frequent than every month would usually not be reasonable.

**L-Dopa Enteral Suspension**
Levodopa-Carbidopa enteral suspension (J7340) is only covered for treatment of motor fluctuations in beneficiaries with Parkinson’s disease (PD), who meet all of the following criteria:
- The beneficiary has been evaluated by a neurologist, who prescribes and manages treatment with the drug; and,
- Idiopathic PD based on the presence of bradykinesia and at least one other cardinal PD features (tremor, rigidity, postural instability); and,
- L-dopa responsive with clearly defined “On” periods; and,
- Persistent motor complications with disabling “Off” periods for a minimum of 3 hours/day, despite medical therapy with levodopa-carbidopa, and at least one other class of anti-PD therapy i.e. COMT inhibitor or MAO-B inhibitor.

Levodopa-Carbidopa enteral suspension is not reasonable and necessary for patients with any of the following:
- Atypical Parkinson’s syndrome ("Parkinson’s Plus” syndrome) or secondary Parkinson’s; or,
- Non-levodopa responsive PD; or,
- Contraindication to percutaneous endoscopic gastro-jejunal (PEG-J) tube placement or long-term use of a PEG-J.

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
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<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
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<tr>
<td>J7340</td>
<td>Carbidopa 5 mg/levodopa 20 mg enteral suspension 100 ml <em>(Effective 01/01/2016)</em></td>
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<tr>
<th>ICD-10 Diagnosis Code</th>
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**PURPOSE**

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:
- Medicare coding or billing requirements, and/or
• Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES

**CMS National Coverage Determinations (NCDs)**
NCD 160.17 L-Dopa

**CMS Local Coverage Determinations (LCDs)**

<table>
<thead>
<tr>
<th>LCD</th>
<th>CGS</th>
<th>DME MAC</th>
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<tr>
<td>L33794 (External Infusion Pumps)</td>
<td>AL, AR, CO, FL, GA, IL, IN, KY, LA, MC, MI, MN, MS, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV</td>
<td>Noridian: AK, AS, AZ, CA (Entire State), CT, DC, DE, GA, HI, IA, ID, KS, MA, MD, ME, MO (Entire State), MP, MT, ND, NE, NH, NJ, NV, NY (Entire State), OR, PA, RI, SD, UT, VT, WA, WY</td>
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**CMS Benefit Policy Manual**

- Chapter 1; § 30 Drugs and Biologicals
- Chapter 6; § 20.4.1 Diagnostic Services Defined
- Chapter 8; § 50.5 Drugs and Biologicals

**GUIDELINE HISTORY/REVISION INFORMATION**

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

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<tr>
<th>Date</th>
<th>Action/Description</th>
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<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
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<tr>
<td>09/12/2018</td>
<td>• Annual review, ICD added</td>
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**TERMS AND CONDITIONS**

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care...
services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member’s benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.