CERTAIN DRUGS DISTRIBUTED BY THE NATIONAL CANCER INSTITUTE (NCD 110.2)

Guideline Number: MPG046.04

Narrative:

Overview
Under its Cancer Therapy Evaluation, the Division of Cancer Treatment of the National Cancer Institute (NCI), in cooperation with the Food and Drug Administration, approves and distributes certain drugs for use in treating terminally ill cancer patients. One group of these drugs, designated as Group C drugs, unlike other drugs distributed by the NCI, are not limited to use in clinical trials for the purpose of testing their efficacy. Drugs are classified as Group C drugs only if there is sufficient evidence demonstrating their efficacy within a tumor type and that they can be safely administered.

Guidelines
A physician is eligible to receive Group C drugs from the Division of Cancer Treatment only if the following requirements are met:
- A physician must be registered with the NCI as an investigator by having completed an FD-Form 1573;
- A written request for the drug, indicating the disease to be treated, must be submitted to the NCI;
- The use of the drug must be limited to indications outlined in the NCI’s guidelines; and
- All adverse reactions must be reported to the Investigational Drug Branch of the Division of Cancer Treatment.

In view of these NCI controls on distribution and use of Group C drugs, A/B Medicare Administrative Contractors (MACs) may assume, in the absence of evidence to the contrary, that a Group C drug and the related hospital stay are covered if all other applicable coverage requirements are satisfied.

If there is reason to question coverage in a particular case, the matter should be resolved with the assistance of the Quality Improvement Organization (QIO), or if there is none, the assistance of the MAC’s medical consultants.

Information regarding those drugs which are classified as Group C drugs may be obtained from:
- Chief, Investigational Drug Branch
- Cancer Therapy Evaluation Program
- Executive Plaza North, Suite 7134
- National Cancer Institute
- Rockville, Maryland 20852-7426

FDA: US Food and Drug Association: The "Group C" treatment IND was established by agreement between FDA and the National Cancer Institute (NCI). The Group C program is a means for the distribution of investigational agents to oncologists for the treatment of cancer under protocols outside the controlled clinical trial. Group C drugs are generally Phase 3 study drugs that have shown evidence of relative and reproducible efficacy in a specific tumor type. They can generally be administered by properly trained physicians without the need for specialized supportive care facilities. Group C drugs are distributed only by the National Institutes of Health under NCI protocols. Although treatment is the primary objective and patients treated under Group C guidelines are not part of a clinical trial, safety and effectiveness data are collected. Because administration of Group C drugs is not done with research intent, FDA has generally granted a waiver from the IRB review requirements [21 CFR 56.105]. Even though FDA has granted a waiver for these drugs, an IRB may still choose to conduct a review under its policies and procedures. The usage of a
Group C drug is described in its accompanying "Guideline Protocol" document. The Guideline Protocol contains an FDA-approved informed consent document which must be used if there has been no local IRB review.

**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 110.2 Certain Drugs Distributed by the National Cancer Institute

**CMS Claims Processing Manual**
Chapter 17; § 80 Claims Processing for Special Drug Categories

**Others**
FDA: US Food and Drug Association, Treatment Use of Investigational Drugs Information Sheet, FDA Website
National Cancer Institute, Clinical Trials Information for Patients and Caregivers, National Cancer Institute Website
National Cancer Institute, Treatment, National Cancer Institute Website

**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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
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<tbody>
<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>10/10/2018</td>
<td>• Annual review</td>
</tr>
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</table>

**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.