

CHEMOTHERAPY OBSERVATION OR INPATIENT HOSPITALIZATION

Guideline Number: URG-02

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INSTRUCTIONS FOR USE

This Utilization Review Guideline provides assistance interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage or Summary Plan Description) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this Guideline. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Guideline. Other policies and guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its policies and guidelines as necessary. This Guideline 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.

UTILIZATION MANAGEMENT GUIDING PRINCIPLES

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 (such as maternity benefits), 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 guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

Introduction:

Most cancer chemotherapies can be administered safely and effectively in a physician office or through home healthcare services. However, because of the risk of certain toxicities or patient co-morbidities, some cancer chemotherapy may be administered either in a facility observation unit or an inpatient unit.

Observation or Overnight Stay

TACE (transcatheter arterial chemoembolization): This procedure is one form of treatment for primary or secondary liver neoplasms. Various chemotherapy drugs are administered through a catheter into the feeding artery of a tumor in the liver, the drugs can including Adriamycin, Cisplatin, etc. This procedure is performed by an interventional radiologist usually at a hospital radiology suite and requested by a radiologist or a radiology department.

1. Please refer to MCG™ Care Guidelines, 18th edition, 2014, Chemotherapy: Observation Care OCG: OC-008 (ISC) for generic observation criteria. The following drugs may require an observation unit stay:
 - a. **Methotrexate** > 500 mg/m². Requires hydration, urinary alkalization and folate rescue. May be used with other drugs.
 - b. **Campath® (alemtuzumab)**. The drug has a 40% hypersensitivity reaction rate.
 - i. Nursing care must be immediately available to manage potential hypersensitivity reaction
 - ii. May be administered in a physician office if professional staff and equipment are available to manage hypersensitivity reaction
 - c. **Cisplatin** (high-dose) > 75 mg/m²
 - d. **Other complex multiple-drug or multiple-day regimens such as ESHAP or EPOCH, Einhorn regimen**

The following are clinical conditions or complications of cancer chemotherapy which, when present, may require an observation stay:

- a. **Known hypersensitivity reactions from previous infusion**
 - i. Nursing care must be immediately available
 - ii. May be administered in a physician office if professional staff and equipment are available
 - b. **Congestive heart failure or chronic renal failure** requiring high volume fluid infusions.
 - i. Assess for performance status
 - c. **Intra-arterial hepatic infusion**
 - i. Sites other than the liver require case-by-case review
 - d. **Comorbidities** that of themselves require an observation or overnight stay
 - i. Review on a case by case basis
 - e. **Cancer chemotherapy administered during a hospitalization** for an unrelated problem
 - f. **Other conditions require case-by-case review**
2. Please refer to MCG™ Care Guidelines, 18th edition, 2014, Chemotherapy: ORG: M-87 (ISC) and MCG™ Care Guidelines, 18th edition, 2014, Neutropenia after Chemotherapy ORG: P-300 (ISC) for generic inpatient admission criteria for administration of chemotherapy. The following drugs may require an observation stay or inpatient hospital stay:
 - a. **Interleukin 2**. Infusions
 - i. Requires cardiac monitoring and clinical assessment.
 - b. **Ifosphamide** 5 day infusions (usually given consecutive days).
 - i. Comorbidities that of themselves require an inpatient stay
 1. Review on a case by case basis
 - ii. Complex chemotherapy programs requiring more than 6 hours of continuous observation and drug administration

- iii. Prevention of a significant adverse event that occurred during a prior outpatient administration
- c. The following are clinical conditions which require an inpatient hospital stay:
 - i. Acute leukemia induction therapy or consolidation therapy.
 - ii. Intra-arterial infusion of chemotherapy. Medical director should review for any site other than liver. Some infusion protocols are more than one day.
 - iii. Prophylaxis of tumor lysis syndrome. Must have diagnosis of lymphoma (high grade with large masses). Must have lab evaluations every 6 hours for potassium, calcium and renal function.
 - iv. Conditions other than these with potential for complications requiring inpatient hospital treatment require case-by-case review.
- 3. Please refer to MCG™ Care Guidelines, 18th edition, 2014, Chemotherapy: ORG: M-2087 (HC) and MCG™ Care Guidelines, 18th edition, 2014, Neutropenia after Chemotherapy ORG: P-2300 (HC) for criteria for admission to home health services for all the above drugs or therapeutic agents.
- 4. Please refer to MCG™ Care Guidelines, 18th edition, 2014 Infusion Pump: ACG: A-0618(AC) for use of infusion pump for delivery of chemotherapy and therapeutic agents.

Additional Review Points:

- 1. A written protocol will be expected to be followed by the provider administering the chemotherapy drug.
- 2. Any requests for an extension of the inpatient stay beyond the recommended day (s) must be clinically reviewed.

DEFINITIONS

Observation Care: Well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. (CMS Medicare)

REFERENCES

- 1. Drugs at FDA @ <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>
- 2. Chemocare (Cleveland Clinic Foundation) @ <http://www.chemocare.com/bio/interleukin.asp>
- 3. Medicare Benefit Policy Manual, Chapter 6 – Hospital Services Covered Under Part B, section 20.6 – Outpatient Observation Services, A. Outpatient Observation Services Defined: @ <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c06.pdf>

GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
06/01/2014	<ul style="list-style-type: none"> • Updated UM guiding principles for observation or overnight stay: <ul style="list-style-type: none"> ○ Added service description for transcatheter arterial chemoembolization (TACE) to indicate: <ul style="list-style-type: none"> ▪ This procedure is one form of treatment for primary or secondary liver neoplasms ▪ Various chemotherapy drugs are administered through a catheter into the feeding artery of a tumor in the liver, the drugs can including Adriamycin, Cisplatinum, etc. ▪ This procedure is performed by an interventional radiologist usually at a hospital radiology suite and requested by a radiologist or a radiology department. ○ Replaced references to “MCG™ Care Guidelines, 17th

Date	Action/Description
	edition, 2013” with “MCG™ Care Guidelines, 18th edition, 2014” <ul style="list-style-type: none"><li data-bbox="565 262 1096 289">• Archived previous policy version URG-02