INSTRUCTIONS FOR USE

This Utilization Review Guideline 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 Utilization Review Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Utilization Review Guideline. 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 Utilization Review Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Utilization Review Guideline is provided for informational purposes. It does not constitute medical advice. This guideline does not govern Medicare Group Retiree members.

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 guideline, please check the member specific benefit plan document and any federal or state mandates, if applicable.

For self-funded plans with SPD language other than fully-insured Generic COC language, please refer to the member specific benefit plan document for coverage.

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 guideline, it is important to refer to the member specific benefit plan document to determine benefit coverage.

UTILIZATION MANAGEMENT GUIDING PRINCIPLES

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 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.

For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 22nd edition, 2018, Chemotherapy: Observation Care OCG: OC-008 (ISC) for generic observation criteria.

The following drugs may require an observation unit stay:
1. Campath® (alemtuzumab)
   - The drug has a 40% hypersensitivity reaction rate
   - Nursing care must be immediately available to manage potential hypersensitivity reaction
   - May be administered in a physician office if professional staff and equipment are available to manage hypersensitivity reaction
2. Cisplatin (high-dose) > 75 mg/m2
3. Other complex multiple-drug or multiple-day regimens such as Hyper-CVAD, ESHAP or EPOCH, Einhorn regimen

The following are clinical conditions or complications of cancer chemotherapy which, when present, may require an observation stay:
1. Known hypersensitivity reactions from previous infusion
   - Nursing care must be immediately available
   - May be administered in a physician office if professional staff and equipment are available
2. Congestive heart failure or chronic renal failure requiring high volume fluid infusions
   - Assess for performance status
3. Intra-arterial hepatic infusion
   - Sites other than the liver require case-by-case review
4. Comorbidities that of themselves require an observation or overnight stay
   - Review on a case-by-case basis
5. Cancer chemotherapy administered during a hospitalization for an unrelated problem
6. Other conditions require case-by-case review

For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 22nd edition, 2018, Chemotherapy: ORG: M-87 (ISC) and MCG™ Care Guidelines, 22nd edition, 2018, 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:
1. Interleukin 2 Infusions
   - Requires cardiac monitoring and clinical assessment
2. Ifosfamide infusions >1g/m2/day (usually given consecutive days)
3. Methotrexate > 500 mg/m2
   - Requires hydration, urinary alkalinization and folate rescue
   - May be used with other drugs
4. Review on a case-by-case basis:
   - Complex multiple-drug chemotherapy regimens requiring more than 6 hours of continuous observation and drug administration such as Hyper-CVAD, ESHAP or EPOCH, Einhorn regimen
   - Prevention of a significant adverse event that occurred during a prior outpatient administration

The following are clinical conditions which require an inpatient hospital stay:
1. Acute leukemia induction therapy or consolidation therapy
2. Intra-arterial infusion of chemotherapy
   - Medical director should review for any site other than liver
   - Some infusion protocols are more than one day
3. Prophylaxis of tumor lysis syndrome
   - Must have lab evaluations every 6 hours for potassium, calcium and renal function
   - Must have diagnosis of lymphoma (high grade with large masses)
4. Comorbidities that of themselves require an inpatient stay
5. Conditions other than these with potential for complications requiring inpatient hospital treatment require case-by-case review
For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 22nd edition, 2018, Chemotherapy: ORG: M-2087 (HC) and MCG™ Care Guidelines, 22nd edition, 2018, Neutropenia after Chemotherapy ORG: P-2300 (HC) for criteria for admission to home health services for all the above drugs or therapeutic agents.

For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 22nd edition, 2018, Infusion Pump: ACG: A-0618(AC) for use of infusion pump for delivery of chemotherapy and therapeutic agents.

Additional Review Points
- A written protocol will be expected to be followed by the provider administering the chemotherapy drug.
- 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


GUIDELINE HISTORY/REVISION INFORMATION

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