CHEMOTHERAPY OBSERVATION OR INPATIENT HOSPITALIZATION

Guideline Number: URG-02.07
Effective Date: May 1, 2020

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Related Commercial Policy
- Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements

COVERAGE RATIONALE

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 individual comorbidities, some cancer chemotherapy may be administered either in a facility observation or inpatient unit.

An inpatient stay is medically necessary for drug regimens that require inpatient monitoring or complex administration over multiple days:

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Drugs</th>
<th>Cancer Type</th>
<th>Factors contributing to the need for inpatient stay:</th>
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</thead>
</table>
| EPOCH or DA-EPOCH or R-EPOCH | • Etoposide 50 mg/m²/day continuous infusion on days 1 to 4  
• Prednisone  
• Vincristine (Oncovine) IV days 1-4  
• Cyclophosphamide 750 mg/m² IV on day 5  
• Doxorubicin (Hydroxydaunorubicin) 10 mg/m²/day continuous infusion on days 1-4  
• With or without Rituximab | Lymphoma | • Coordination of multiple infusions or multiple drugs over 96 hours |
| ESHAP or R-ESHAP | • Etoposide 40 mg/m²/day continuous infusion on days 1 to 4  
• Methylprednisolone (solumedrol)  
• Cytarabine ("High-dose Ara-c") 2g/m²  
• Cisplatin (platinol) 25mg/m continuous infusion days 1-4  
• With or without Rituximab | Lymphoma | • Coordination of multiple infusions or multiple drugs over 96 hours  
• Monitor for CNS toxicity with cytarabine |
<table>
<thead>
<tr>
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<th>Factors contributing to the need for inpatient stay:</th>
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</table>
| Interleukin 2 infusion                       | • Interleukin 2 600,000 IU/kg IV every 8 hours for up to 14 consecutive doses over 5 days                                                                                                               | Melanoma Renal Cell Cancer  | • Continuous cardiac monitoring  
• Close monitoring of serum electrolytes, creatinine, bilirubin, urine output  
• Vasopressor support with dopamine  
• Proximity to intensive care unit |
| High dose Ifosphamide                        | • Ifosphamide infusion > 1g/m2/day                                                                                                                                                                      | Sarcoma                     | • Close monitoring of serum electrolytes and urine pH  
• Replacement of electrolytes  
• Alkalization of urine                                                                                                                                                           |
| High dose methotrexate with leucovorin rescue| • Methotrexate dose at > 500 mg/m2  
• Leucovorin 15 mg every 6 hours for eight doses beginning 12 hours after the completion of methotrexate infusion, and increased to 50 mg IV every 6 hours if methotrexate levels are >20 µmol/L at 0 hour, are >1.0 µmol/L at 24 hours, or are >0.1 µmol/L at 48 hours after the end of methotrexate infusion, until levels are <0.1 µmol/L plus | Lymphoma Sarcoma            | • Close monitoring of serum methotrexate levels                                                                                                                                 |
| Hyper-CVAD                                    | • Cycles 1, 3, 5, and 7 (3-4 weeks between cycles):  
• Cyclophosphamide 300 mg/m² IV over 2 hours every 12 hours for 6 doses  
• Mesna 600 mg/m²/day continuous infusion on days 1-3, starting 1 hour before cyclophosphamide  
• Vincristine  
• Doxorubicin 50 mg/m² IV on day 4  
• Dexamethasone  
• Cycles 2, 4, 6, and 8 (3-4 weeks between cycles):  
• Methotrexate 200 mg/m² IV over 2 hours followed by 800 mg/m² IV over 22 hours on day 1 plus  
• Cytarabine 3 g/m² (1 g/m² for patients older than 60 years) IV over | Lymphoma Leukemia           | • Coordination of multiple infusions or multiple drugs over 96 hours  
• Bladder irrigation with cyclophosphamide  
• Close monitoring of serum methotrexate levels                                                                                                                                 |
The following are clinical conditions or complications of cancer chemotherapy which, when present, may require an observation stay:

- Known hypersensitivity reactions from previous infusion
- Congestive heart failure or chronic renal failure requiring high volume fluid infusions
- Transcatheter arterial chemoembolization (TACE) or intra-arterial chemotherapy infusion
- Comorbidities that require an observation or overnight stay
- Cancer chemotherapy administered during a hospitalization for an unrelated problem

The following are clinical conditions which require an inpatient hospital stay:

- Acute leukemia
- Intra-arterial infusion of chemotherapy
- Prophylaxis of tumor lysis syndrome in cases of high grade lymphoma with large masses
- Comorbidities that require an inpatient stay

Conditions requiring observation or inpatient hospital treatment other than those noted above will be reviewed on a case-by-case basis.

For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 24th edition, 2020, for the following:

- Observation care criteria for chemotherapy: Chemotherapy: Observation Care OCG: OC-008 (ISC)
- Inpatient admission criteria for administration of chemotherapy: Chemotherapy: ORG: M-87 (ISC) and Neutropenia after Chemotherapy ORG: P-300 (ISC)
- Admission to home health services for all the above drugs or therapeutic agents: Chemotherapy: ORG: P-2300 (HC)
- Use of infusion pump for delivery of chemotherapy and therapeutic agents: Infusion Pump: ACG: A-0618(AC)

Click here to view the MCG™ Care Guidelines.

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.

DESCRIPTION OF SERVICES

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 an individual will require further treatment as a hospital inpatient or if they are able to be discharged (CMS Medicare).
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, 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.

REFERENCES


GUIDEline HISTORY/REVISON INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>05/01/2020</td>
<td>Coverage Rationale</td>
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<tr>
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<td>• Removed language indicating the following drugs may require observation or inpatient hospital stay:</td>
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<tr>
<td></td>
<td>o Campath® (alemtuzumab)</td>
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<td></td>
<td>o Cisplatin (high-dose) &gt; 75 mg/m2</td>
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<td></td>
<td>o Interleukin 2 infusion</td>
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<td></td>
<td>o Ifosfamide infusion &gt; 1g/m2/day (usually given consecutive days)</td>
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<tr>
<td></td>
<td>o Methotrexate &gt; 500 mg/m2</td>
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<td></td>
<td>o Other complex multiple-drug or multiple-day regimens such as Hyper-CVAD, ESHAP or EPOCH, Einhorn regimen</td>
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<td>• Added language to indicate an inpatient stay is medically necessary for drug regimens that require inpatient monitoring or complex administration over multiple days</td>
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<td>• Added list of drug regimens with corresponding drug products, cancer types, and factors contributing to the need for inpatient stay:</td>
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<td>o High dose methotrexate with leucovorin rescue</td>
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<td>o Hyper-CVAD</td>
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<td>• Revised list of clinical conditions which require an inpatient hospital stay; replaced “acute leukemia induction therapy or consolidation therapy” with “acute leukemia”</td>
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Supporting Information

• Archived previous policy version URG-02.06

INSTRUCTIONS FOR USE

This Utilization Review Guideline provides assistance in interpreting UnitedHealthcare standard 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 plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, 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 Utilization Review 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. UnitedHealthcare Utilization Review 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.