Temodar® (temozolomide)

Medical Guideline Disclaimer

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Definition

Temodar is an alkylating antineoplastic agent. Temodar undergoes rapid chemical conversion at physiologic pH to the active compound, monomethyl triazeno imidazole carboxamide (MTIC). The cytotoxicity of MTIC is thought to be due primarily to methylation of DNA at the O6 and N7 positions of guanine. The formation of Omethylguanine inhibits DNA replication through errant repair of the methyladduct and causes cell death via stimulation of p53 and apoptosis. Temodar is cell-cycle non-specific; however, cell cycle arrest usually occurs between the G2- and M-phases. The combination of Temodar (temozolomide) and radiation therapy results in additive effects.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:

- 200 mg/m2/day

I. Initial Approval Criteria

Temodar may be considered medically necessary if one of the below conditions are met AND use is consistent with the medical necessity criteria that follows:

- Patient age is ≥ 18 years old; AND
- Prescribed by or in consultation with an oncologist; AND
- Dose does not exceed 200 mg/m2/day; AND
- Patient has medical documentation for one of the following indications:
  1. Glioblastoma
  2. Anaplastic Astrocytoma
Limitations/Exclusions

Temodar is not considered medically necessary when any of the following selection criteria is met:

1) Disease progression while on Temodar (temozolimide).
2) Dosing exceeds single dose limit of 200 mg/m2/day.
3) Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA

- Patient continues to meet INITIAL APPROVAL CRITERIA.
- Tumor response with disease stabilization or reduction of tumor size and spread.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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| Glioblastoma                | - **Concomitant phase:** 75 mg/m2 daily for 42 days concomitant with focal radiotherapy (60 Gy administered in 30 fractions) followed by maintenance Temodar for 6 cycles.  
- **Maintenance phase:**  
  **Cycle 1:** Four weeks after completing the Temodar+RT phase, Temodar is administered for an additional 6 cycles of maintenance treatment. Dosage in Cycle 1 (maintenance) is 150 mg/m2 once daily for 5 days followed by 23 days without treatment.  
  **Cycles 2-6:** At the start of Cycle 2, the dose can be escalated to 200 mg/m2. The dose remains at 200 mg/m2 per day for the first 5 days of each subsequent cycle except if toxicity occurs. If the dose was not escalated at Cycle 2, escalation should not be done in subsequent cycles. |
| Anaplastic astrocytoma      | - Initial dose is 150 mg/m2 once daily for 5 consecutive days per 28-day treatment cycle. |

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Billable Unit</th>
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<tbody>
<tr>
<td>J9328</td>
<td>Injection, temozolomide, 1 mg</td>
<td>1 mg</td>
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Applicable NDCs

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>00085-1381-xx</td>
<td>Temodar single use vial; 100 mg powder for solution</td>
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## Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>C71.0 - C71.9</td>
<td>Malignant neoplasm of brain [intracranial ependymoma] [adult low-hyphengrade infiltrative supratentorial astrocytoma/oligodendrogloma] [adult medulloblastoma or supratentorial primitive neuroectodermal tumors (PNET)] [anaplastic gliomas] [glioblastoma]</td>
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<tr>
<td>C72.0 C72.9</td>
<td>Malignant neoplasm of central nervous system [anaplastic gliomas, glioblastoma, adult low-hyphengrade infiltrative supratentorial astrocytoma/oligodendrogloma (excluding pilocytic astrocytoma)]</td>
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## References