Primary Mediastinal Large B-Cell Lymphoma

Disclaimer: This algorithm has been developed for MD Anderson using a multidisciplinary approach considering circumstances particular to MD Anderson’s specific patient population, services and structure, and clinical information. This is not intended to replace the independent medical or professional judgment of physicians or other health care providers in the context of individual clinical circumstances to determine a patient’s care. This algorithm should not be used to treat pregnant women.

Note: Consider Clinical Trials as treatment options for eligible patients.

PATHOLOGIC DIAGNOSIS

ESSENTIAL:
- Hematopathology review of all slides with at least one paraffin block or 15 unstained slides representative of the tumor. Rebiopsy if consult material is nondiagnostic.
- Adequate morphology and immunophenotyping to establish diagnosis
  - Paraffin Panel: CD3, CD20 and/or another pan-B-cell marker (CD19, PAX-5, CD79a)
  - Flow cytometry immunophenotypic studies: CD45 (LCA), CD3, CD5, CD10, CD19, CD20, CD22, kappa and lambda light chains
- Additional immunohistochemical studies as needed:
  - PD-L1/L2, CD5, CD10, CD15, CD23, CD45, CD79a, BCL-2, BCL-6, MUM-1/IRF4, and MIB1 (Ki67).

OF USE IN CERTAIN CIRCUMSTANCES:
- EBER in situ hybridization, LMP-1, HHV-8, CD138, CD30, TdT and ALK1
- FISH studies to detect gene rearrangements; involving: MYC, BCL-2 and/or BCL-6
- Molecular studies to detect clonality of the IgH gene

STRONGLY RECOMMENDED:
- FNA or core biopsy for tissue array/banking by protocol

INITIAL EVALUATION

ESSENTIAL:
- Physical exam: attention to node-bearing areas, including Waldeyer's ring, and to size of liver and spleen
- ECOG performance status
- B symptoms (Unexplained fever >38°C during the previous month; Recurrent drenching night sweats during the previous month; Weight loss >10 percent of body weight ≤ 6 months of diagnosis)
- CBC with differential, LDH, BUN, creatinine, albumin, AST, ALT, total bilirubin, alkaline phosphatase, serum calcium, uric acid
- Beta 2 microglobulin
- Screening for HIV 1 and 2, hepatitis B and C (HBcAb, HBsAg, HCV Ab)
- Chest x-ray, PA and LAT
- CT with contrast of neck, chest, abdomen and pelvis
- Unilateral or bilateral bone marrow biopsy with or without aspirate
- Calculation of IPI
- Muga scan or echocardiogram
- PET/CT
- Discuss fertility issues and sperm banking for patients of child bearing potential
- Lifestyle risk assessment

OF USE IN SELECTED CASES:
- CT or MRI of head, and MRI of the spine (only if clinical suspicion of involvement with lymphoma)
- Pregnancy test
- Consider lumbar puncture and intrathecal chemotherapy if paranasal sinus, testicular, epididural, ≥ 2 extranodal sites, or if IPI score ≥ 3
- Consider thoracentesis if clinically indicated

See Page 2, Induction Therapy
INDUCTION THERAPY

All stages $\rightarrow$ DAEPOCH-R\(^1\) for 6 cycles $\rightarrow$ Evaluate response after 2 cycles by PET scan $\rightarrow$ Patient has greater than or equal to partial response? $^	ext{2}\rightarrow$

Yes $\rightarrow$ Continue planned treatment $\rightarrow$ See Page 3, Post-treatment Response Evaluation

No $\rightarrow$ Core needle or excisional biopsy $\rightarrow$ Biopsy positive?

Yes $\rightarrow$ See Page 4, Relapse or Refractory Treatment

No $\rightarrow$ Continue planned treatment

---

1 DAEPOCH-R: dose adjusted EPOCH-R: etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin and rituximab (see Appendix B); administration is based on age and performance status of the patient

2 See Appendix C: Revised Criteria for Response Assessment
Primary Mediastinal Large B-Cell Lymphoma

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Note: Consider Clinical Trials as treatment options for eligible patients.

RESPONSE EVALUATION

Complete response¹
5PS score 1-3²

Multidisciplinary conference and/or follow-up evaluation if previous bulky mass³ or large residual non-fluorodeoxyglucose (FDG) avid mass

Complete treatment

History and physical with CT neck, chest, abdomen, and pelvis with contrast and labs as clinically indicated:
- Every 3 to 4 months for 1 year, then
- Every 6 months for 2 years, then
- Annual PA and LAT CXR

Partial response¹
5PS score 4²
PET – equivocal⁴

• Repeat PET scan in 6-8 weeks
• Consider biopsy of residual mass only if high clinical suspicion or close imaging follow up not feasible
• Consider Radiation Oncology evaluation

PET normalized?

Yes

Multidisciplinary conference and/or consider Radiation Oncology evaluation if previous bulky mass² or large residual non-FDG avid mass

Complete treatment

No

Biopsy positive?

Yes

See Page 4, Relapse or Refractory Treatment

No

Biopsy negative?

No

Biopsy positive?

Yes

See Page 4, Relapse or Refractory Treatment

No

Multidisciplinary conference and/or consider Radiation Oncology evaluation if:
- Biopsy or residual mass negative though high clinical/radiographic suspicion
- Biopsy of residual mass is not possible due to location/patient refusal with high clinical/radiographic suspicion

¹ See Appendix C: Revised Criteria for Response Assessment
² See Appendix D: 5-Point Scale (5PS)
³ Bulky disease: mass ≥ 7.5 cm on CT imaging
⁴ PET equivocal: maximum standardized uptake value (SUV) greater than mediastinal blood pool in the residual mediastinal mass

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Primary Mediastinal Large B-Cell Lymphoma

Consolidation/Additional Therapy

Relapse or refractory

Patient candidate for high dose therapy

Patient not a candidate for high dose therapy

Relapse or refractory

Clinical trial

New non cross-resistant regimen, chemo-immunotherapy (e.g., rituximab with one of the following regimens: ICE, ESHAP, MINE, DHAP)

Consider radiation therapy for consolidation with involved site approach

Patient has greater than or equal to partial response?  

Yes

High dose therapy plus autologous or allogeneic stem cell transplant (in the context of a clinical trial)

No

Patient candidate for intensive therapy?

Yes

Clinical trial

Standard of care chimeric antigen receptor (CAR) T-cell therapy

No

Individual approach including:

Clinical trial*, palliative chemotherapy or palliative radiation therapy

Note: Consider Clinical Trials as treatment options for eligible patients.

ICE = ifosfamide, carboplatin, etoposide
ESHAP = etoposide, methylprednisolone, high-dose cytarabine, cisplatin
MINE = mesna, ifosfamide, mitoxantrone, etoposide
DHAP = dexamethasone, cytarabine, cisplatin

1 See Appendix C: Revised Criteria for Response Assessment

2 Clinical trials or individual regimens: except for patients with disease-free interval, those who progress after three successive regimens are unlikely to derive additional benefit from currently utilized combination chemotherapy regimens

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## APPENDIX A: International Prognostic Index (IPI)

### Pre-Treatment Characteristics, ALL PATIENTS:
- Age > 60 years old
- Serum LDH greater than upper limit of normal
- ECOG performance status 2-4
- Stage III or IV
- Extranodal involvement > 1 site

### International Index, ALL PATIENTS:

<table>
<thead>
<tr>
<th>Number of characteristics</th>
<th>Low</th>
<th>Low intermediate</th>
<th>High intermediate</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 or 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 or 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Age-Adjusted IPI

### Pre-Treatment Characteristics, ALL PATIENTS ≤ 60 YEARS:
- Serum LDH greater than one times upper limit of normal
- ECOG performance status 2-4
- Extranodal involvement > 1 site

### International Index, ALL PATIENTS ≤ 60 YEARS:

<table>
<thead>
<tr>
<th>Number of characteristics</th>
<th>Low</th>
<th>Low intermediate</th>
<th>High intermediate</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
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<tr>
<td>2</td>
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<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX B: Dose Adjusted EPOCH-R

**Table 1. EPOCH-R starting dose level**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose, route, treatment days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rituximab</td>
<td>375 mg/m² IV day 1</td>
</tr>
<tr>
<td>Etoposide</td>
<td>50 mg/m²/day continuous IV days 1-4</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>10 mg/m²/day continuous IV days 1-4</td>
</tr>
<tr>
<td>Vincristine</td>
<td>0.4 mg/m²/day continuous IV days 1-4</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>750 mg/m²/day IV day 5</td>
</tr>
<tr>
<td>Prednisone</td>
<td>60 mg/m² PO twice daily days 1-5</td>
</tr>
<tr>
<td>Filgrastim product</td>
<td>5 mcg/kg subcutaneously daily starting on day 6 until ANC &gt; 5 K/microliter</td>
</tr>
<tr>
<td>Next Cycle¹</td>
<td>Day 21</td>
</tr>
</tbody>
</table>

1 Begin on day 21 if the ANC ≥ 1 K/microliter and the platelet count ≥ 100 K/microliter

**Table 2. EPOCH dose-adjustment paradigm**

<table>
<thead>
<tr>
<th>Nadir measurements²</th>
<th>Dose-adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>If nadir ANC ≥ 0.5 K/microliter</td>
<td>20% increase in etoposide, doxorubicin and cyclophosphamide above last cycle</td>
</tr>
<tr>
<td>If nadir ANC &lt; 0.5 K/microliter on 1 or 2 measurements</td>
<td>Same doses as last cycle</td>
</tr>
<tr>
<td>If nadir ANC &lt; 0.5 K/microliter on at least 3 measurements or</td>
<td>20% decrease in etoposide, doxorubicin and cyclophosphamide below last cycle</td>
</tr>
<tr>
<td>If nadir platelet count &lt; 25 K/microliter on 1 measurement</td>
<td></td>
</tr>
</tbody>
</table>

Note: Dose adjustments above starting dose level apply to etoposide, doxorubicin and cyclophosphamide. Dose adjustments below starting dose level apply to cyclophosphamide only.

² Measurements of ANC and platelet nadir are based on twice weekly CBC only.
APPENDIX C: Revised Criteria for Response Assessment

<table>
<thead>
<tr>
<th>Response and Site</th>
<th>PET-CT-Based Response</th>
<th>CT-Based Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete</td>
<td>Complete metabolic response</td>
<td>Complete radiologic response (all of the following)</td>
</tr>
<tr>
<td>Lymph nodes and extralymphatic sites</td>
<td>Score 1, 2, or 3 with or without a residual on 5PS(^5)</td>
<td>Target nodes/nodal masses must regress to (0.5 \text{ cm} ) in LDi</td>
</tr>
<tr>
<td></td>
<td>It is recognized that in Waldeyer’s ring or extranodal sites with high physiologic uptake or with activation within spleen or marrow (e.g., with chemotherapy or myeloid colony-stimulating factors), uptake may be greater than normal mediastinum and/or liver. In this circumstance, complete metabolic response may be inferred if uptake at sites of initial involvement is no greater than surrounding normal tissue even if the tissue has high physiologic uptake.</td>
<td>No extralymphatic sites of disease</td>
</tr>
<tr>
<td>Nonmeasured lesion</td>
<td>Not applicable</td>
<td>Absent</td>
</tr>
<tr>
<td>Organ enlargement</td>
<td>Not applicable</td>
<td>Regress to normal</td>
</tr>
<tr>
<td>New lesion</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>No evidence of FDG-avid disease in marrow</td>
<td>Normal by morphology; if indeterminate, IHC negative</td>
</tr>
</tbody>
</table>

Abbreviations: 5PS, 5-point scale; CT, computed tomography; FDG, fluorodeoxyglucose; IHC, immunohistochemistry; LDi, longest transverse diameter of a lesion; MRI, magnetic resonance imaging; PET, positron emission tomography; PPD, cross product of the LDi and perpendicular diameter; SDi, shortest axis perpendicular to the LDi; SPD, sum of the product of the perpendicular diameters for multiple lesions.

\(^5\) A score of 3 in many patients indicates a good prognosis with standard treatment, especially if at the time of an interim scan. However, in trials involving PET where de-escalation is investigated, it may be preferable to consider a score of 3 as inadequate response (to avoid undertreatment). Measured dominant lesions: Up to six of the largest dominant nodes, nodal masses, and extranodal lesions selected to be clearly measurable in two diameters. Nodes should preferably be from disparate regions of the body and should include, where applicable, mediastinal and retroperitoneal areas. Non-nodal lesions include those in solid organs (eg, liver, spleen, kidneys, lungs). GI involvement, cutaneous lesions, or those noted on palpation. Nonmeasured lesions: Any disease not selected as measured, dominant disease and truly assessable disease should be considered not measured. These sites include any nodes, nodal masses, and extranodal sites not selected as dominant or measurable or that do not meet the requirements for measurability but are still considered abnormal, as well as truly assessable disease, which is any site of suspected disease that would be difficult to follow quantitatively with measurement, including pleural effusions, ascites, bone lesions, leptomeningeal disease, abdominal masses, and other lesions that cannot be confirmed and followed by imaging. In Waldeyer’s ring or in extranodal sites (eg, GI tract, liver, bone marrow), FDG uptake may be greater than in the mediastinum with complete metabolic response, but should be no higher than surrounding normal physiologic uptake (eg, with marrow activation as a result of chemotherapy or myeloid growth factors).

\(^5\) PET 5PS: 1, no uptake above background; 2, uptake \(\leq\) mediastinum; 3, uptake \(>\) mediastinum but \(\leq\) liver; 4, uptake moderately \(>\) liver; 5, uptake markedly higher than liver and/or new lesions; X, new areas of uptake unlikely to be related to lymphoma.


**continued on next page**
### APPENDIX C: Revised Criteria for Response Assessment - continued

<table>
<thead>
<tr>
<th>Response and Site</th>
<th>PET-CT-Based Response</th>
<th>CT-Based Response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Partial</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymph nodes and extralymphatic sites</td>
<td>Score 4 or 5 with reduced uptake compared with baseline and residual mass(es) of any size At interim, these findings suggest responding disease At end of treatment, these findings indicate residual disease</td>
<td>≥ 50% decrease in SPD of up to 6 target measurable nodes and extranodal sites When a lesion is too small to measure on CT, assign 5 mm x 5 mm as the default value When no longer visible, 0 x 0 mm For a node &gt; 5 mm x 5 mm, but smaller than normal, use actual measurement for calculation</td>
</tr>
<tr>
<td>Nonmeasured lesion</td>
<td>Not applicable</td>
<td>Absent/normal, regressed, but no increase</td>
</tr>
<tr>
<td>Organ enlargement</td>
<td>Not applicable</td>
<td>Spleen must be regressed by &gt; 50% in length beyond normal</td>
</tr>
<tr>
<td>New lesion</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>Residual uptake higher than uptake in normal marrow but reduced compared with baseline (diffuse uptake compatible with reactive changes from chemotherapy allowed). If there are persistent focal changes in the marrow in the context of a nodal response, consideration should be given to further evaluation with MRI or biopsy or an interval scan.</td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>No response or stable disease</strong></td>
<td>No metabolic response</td>
<td>Stable disease</td>
</tr>
<tr>
<td>Target nodes/nodal masses, extranodal lesions</td>
<td>Score 4 or 5 with no significant change in FDG uptake from baseline at interim or end of treatment</td>
<td>&lt; 50% decrease from baseline in SPD of up to 6 dominant, measurable nodes and extranodal sites; no criteria for progressive disease are met</td>
</tr>
<tr>
<td>Nonmeasured lesion</td>
<td>Not applicable</td>
<td>No increase consistent with progression</td>
</tr>
<tr>
<td>Organ enlargement</td>
<td>Not applicable</td>
<td>No increase consistent with progression</td>
</tr>
<tr>
<td>New lesion</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>No change from baseline</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Abbreviations: 5PS, 5-point scale; CT, computed tomography; FDG, fluorodeoxyglucose; IHC, immunohistochemistry; LDi, longest transverse diameter of a lesion; MRI, magnetic resonance imaging; PET, positron emission tomography; PPD, cross product of the LDi and perpendicular diameter; SDi, shortest axis perpendicular to the LDi; SPD, sum of the product of the perpendicular diameters for multiple lesions.  
*PET 5PS: 1, no uptake above background; 2, uptake ≤ mediastinum; 3, uptake > mediastinum but ≤ liver; 4, uptake moderately > liver; 5, uptake markedly higher than liver and/or new lesions; X, new areas of uptake unlikely to be related to lymphoma.*  
*PET 5PS: 1, no uptake above background; 2, uptake ≤ mediastinum; 3, uptake > mediastinum but ≤ liver; 4, uptake moderately > liver; 5, uptake markedly higher than liver and/or new lesions; X, new areas of uptake unlikely to be related to lymphoma.*  


Continued on next page
### APPENDIX C: Revised Criteria for Response Assessment - continued

<table>
<thead>
<tr>
<th>Response and Site</th>
<th>PET/CT-Based Response</th>
<th>CT-Based Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progressive disease</td>
<td>Progressive metabolic disease</td>
<td>Progressive disease requires at least 1 of the following</td>
</tr>
<tr>
<td>Individual target nodes/nodal masses</td>
<td>Score 4 or 5 with an increase in intensity of uptake from baseline and/or New FDG-avid foci consistent with lymphoma at interim or end-of-treatment assessment</td>
<td>PPD progression:</td>
</tr>
<tr>
<td>Extranodal lesions</td>
<td></td>
<td>An individual node/lesion must be abnormal with:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• LDi &gt; 1.5 cm and/or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Increase by ≥ 50% from PPD nadir and/or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• An increase in LDi or SDi from nadir:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>○ 0.5 cm for lesions ≤ 2 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>○ 1.0 cm for lesions &gt; 2 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• In the setting of splenomegaly, the splenic length must increase by &gt; 50% of the extent of its prior increase beyond baseline (e.g., a 15-cm spleen must increase to &gt; 16 cm). If no prior splenomegaly, must increase by at least 2 cm from baseline.</td>
</tr>
<tr>
<td>Nonmeasured lesions</td>
<td>None</td>
<td>New or clear progression of preexisting nonmeasured lesions</td>
</tr>
<tr>
<td>New lesion</td>
<td>New FDG-avid foci consistent with lymphoma rather than another etiology (e.g., infection, inflammation). If uncertain regarding etiology of new lesions, biopsy or interval scan may be considered.</td>
<td>Regrowth of previously resolved lesions</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>New or recurrent FDG-avid foci</td>
<td>New or recurrent involvement</td>
</tr>
</tbody>
</table>

Abbreviations: 5PS, 5-point scale; CT, computed tomography; FDG, fluorodeoxyglucose; IHC, immunohistochemistry; LDi, longest transverse diameter of a lesion; MRI, magnetic resonance imaging; PET, positron emission tomography; PPD, cross product of the LDi and perpendicular diameter; SDi, shortest axis perpendicular to the LDi; SPD, sum of the product of the perpendicular diameters for multiple lesions.

# APPENDIX D: 5-Point Scale (5PS)

- Score 1: no uptake
- Score 2: uptake less than or equal to mediastinum
- Score 3: uptake greater than mediastinum but less than or equal to liver
- Score 4: uptake moderately greater than liver
- Score 5: uptake markedly (>2-3X) greater than liver and new sites of disease
- Score X: new areas of uptake unlikely to be related to lymphoma

A score of 1-3 is regarded as negative and 4 or 5 as positive.
SUGGESTED READINGS


Continued on next page
Primary Mediastinal Large B-Cell Lymphoma

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SUGGESTED READINGS - continued


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DEVELOPMENT CREDITS

This practice algorithm is based on majority expert opinion of the Lymphoma Center Faculty at the University of Texas MD Anderson Cancer Center. It was developed using a multidisciplinary approach that included input from the following:

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*Clinical Effectiveness Development Team