Waldenstrom's Macroglobulinemia

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

INITIAL WORK-UP

ESSENTIAL:

- History and physical exam
- CBC with differential, comprehensive metabolic panel, hepatitis B and hepatitis C serology, cryocrit[1], cold agglutinins titer, LDH, beta-2 microglobulin, serum protein electrophoresis and immunofixation, serum free light chain assay (kappa and lambda), and quantitative immunoglobulins (IgG, IgM, IgA)
- 24 hour urine protein electrophoresis and immunofixation
- Unilateral bone marrow aspirate and biopsy
  - CXCR4 and MYD88 L265P AS-PCR
- PET/CT or CT neck, chest, abdomen and pelvis with IV contrast
- Lifestyle risk assessment[2]

USEFUL IN CERTAIN PATIENTS:

- Fundoscopic examination[3]
- Serum viscosity[4]
- Coomb's Test[5]
- Anti-myelin associated glycoprotein (MAG) antibody[6]
- Anti-ganglioside monosialosyl 1 (GM1) antibody[6]
- Electromyogram (EMG)[6]
- Nerve conduction studies (NCS)[6]
- Congo red staining of abdominal fat pad biopsy and/or bone marrow biopsy[6,7]
- Echocardiogram[8]
- Prothrombin time (PT), Activated partial thromboplastin time (aPTT), Factor VIII (FVIII) coagulant activity, Ristocetin cofactor (RCoF) activity and Concentration of vWF antigen (vWF:Ag)[9]
- Brain/Spine MRI[10]
- Lumbar puncture[10]

[1] Cryocrit sample should be maintained at 37°C. If positive, maintain all Serum Protein Electrophoresis (SPEP) samples at 37°C until processed in the lab.

[2] See Physical Activity, Nutrition, and Tobacco Cessation Treatment algorithms; ongoing reassessment of lifestyle risks should be a part of routine clinical practice

Indications for treatment:

- Symptomatic hyperviscosity (eye grounds, neurologic changes)
- Anemia (Hgb < 10 grams/dL) or other cytopenias (due to marrow involvement/ hypersplenism, cold agglutinin hemolytic anemia)
- Bulky adenopathy
- Symptomatic organomegaly
- Symptomatic cryoglobulinemia
- Amyloidosis
- Neuropathy
- Acquired von Willebrand disease
- CNS Involvement (Bing-Neel Syndrome)
- B symptoms (unexplained fever > 38°C during the previous month; Recurrent drenching night sweats during the previous month; Weight loss > 10% of body weight ≤ 6 months of diagnosis)

PRIMARY TREATMENT

- Clinical trial
- Bruton's Tyrosine Kinase (BTK) inhibitor:
  - Zanubrutinib
  - Ibrutinib with or without rituximab[11]
- Proteasome inhibitor based regimen:
  - Bortezomib/rituximab[11] with or without dexamethasone
  - Carfilzomib/rituximab[11] with dexamethasone
- Conventional chemotherapy based regimen:
  - Alkylating agent[12]/rituximab[11]
    - Bendamustine/rituximab
    - Rituximab/cyclophosphamide/ dexamethasone
  - Nucleoside analog[12]/rituximab[11]
    - Cladribine/cyclophosphamide/rituximab
- Single-agent rituximab[11, 13]
- See Appendix A for supportive care measures

See Page 2 for follow-up and surveillance

[3] When hyperviscosity is suspected

[4] Most patients with serum viscosity of < 4 cP will not have symptoms of hyperviscosity

[5] When hemolytic anemia is suspected

[6] When symptoms or signs or peripheral neuropathy present

[7] When amyloidosis suspected

[8] Baseline echocardiogram if treatment risk for cardiac toxicities

[9] If clinical bruising or bleeding present (concern for acquired von Willebrand disease)

[10] When central nervous system involvement suspected

[11] For rituximab intolerant patients, ofatumumab may be substituted in all rituximab containing regimens

[12] Use alkylating agents and nucleoside analog-based regimen with caution in stem cell transplant candidates

[13] The use of single-agent rituximab is discouraged, particularly in patients with M-protein > 5 grams/dL

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Waldenstrom's Macroglobulinemia

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

MANAGEMENT OF DISEASE RELAPSE

FOLLOW-UP/ SURVEILLANCE

- Order the following prior to each cycle during systemic therapy and at least every 3-4 months during periods of observation:
  - CBC with differential
  - SPEP
  - Quantitative immunoglobulins (cryocrit and/or cold agglutinins if initially positive[1])
  - Free kappa and free lambda light chains
  - 24-hour UPEP
- If abnormal finding present during initial work-up scan, order the following every 3-6 months initially, then every 6-12 months:
  - PET/CT or CT neck, chest, abdomen and pelvis with IV contrast

APPROACH TO CHOICE OF SALVAGE TREATMENT

If ≥ partial response achieved (see Appendix B for response), observe until symptomatic or signs of end organ damage develop

Refractory to primary treatment or response to initial therapy with relapse < 12 months

- Choose alternate therapy
- Discuss Goal Concordant Care (GCC) with patient or if clinically indicated, with Patient Representative[2]

Response to initial therapy with relapse ≥ 12 months

- May return to prior therapy **or**
- Choose alternate therapy

RELAPSED/REFRACTORY TREATMENT OPTIONS

- Clinical trial
- BTK inhibitor:
  - Zanubrutinib
  - Ibrutinib with or without rituximab
  - Acalabrutinib
- Proteasome inhibitor based regimen
  - Bortezomib/rituximab with or without dexamethasone
  - Carfilzomib/rituximab with dexamethasone
- Conventional chemotherapy based regimen:
  - Alkylating agent[3]/rituximab
    - Bendamustine/rituximab
    - Rituximab/cyclophosphamide/dexamethasone
  - Nucleoside analog[3]/rituximab
    - Cladribine/cyclophosphamide/rituximab
  - Autologous stem cell transplant
  - Allogeneic stem cell transplant (ablative or non-ablative)
- Monoclonal antibody based regimen:
  - Rituximab[4]
  - Ofatumumab[5]
- B-cell lymphoma 2 (Bcl-2) inhibitor:
  - Venetoclax
- See Appendix A for supportive care measures

SPEP = Serum Protein Electrophoresis
UPEP = Urine Protein Electrophoresis

[1] Cryocrit sample should be maintained at 37°C. If positive, maintain all SPEP samples at 37°C until processed in the lab.
[2] GCC should be initiated by the Primary Oncologist. If Primary Oncologist is unavailable, Primary Team/Attending Physician to initiate GCC discussion and notify Primary Oncologist. Patients, or if clinically indicated, the Patient Representative should be informed of therapeutic and/or palliative options. GCC discussion should be consistent, timely, and re-evaluated as clinically indicated. The Advance Care Planning (ACP) note should be used to document GCC discussion. Refer to GCC home page (for internal use only).
[3] Use alkylating agent and nucleoside analog-based regimens with caution in stem cell transplant candidates
[4] For patients with M-protein > 5 grams/dL, use of rituximab alone is discouraged. Reports of transient increase in M-protein have been noted with the use of rituximab alone.
[5] For rituximab intolerant patients, ofatumumab may be substituted in all rituximab containing regimens

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Waldenstrom's Macroglobulinemia

APPENDIX A: Supportive Care Measures

Infection:

- Intravenous immunoglobulin therapy should be considered in the setting of recurrent life-threatening infection, hypogammaglobulinemia, and/or if ≥ 3 infections/year
- Recommend COVID-19 vaccinations per Centers for Disease Control and Prevention (CDC) guidelines[1]
- Recommend pneumococcal vaccinations per CDC guidelines[1]
- Recommend annual influenza vaccine
  - Recommend high-dose influenza vaccine for patients ≥ 65 years old and patients who have previously undergone a stem cell transplant (SCT)
- Herpes zoster prophylaxis is indicated for patients treated with proteasome inhibitors, daratumumab, and/or high dose dexamethasone
- Anti-Hepatitis B viral therapy is indicated in patients with active hepatitis B and those at risk of reactivation, who will be receiving rituximab or ofatumumab
- Consider avoiding concomitant quinolone therapy for patients on bortezomib-containing regimens
- Antifungal, antibacterial, and anti-zoster prophylaxis is indicated for patients receiving hyper fractionated cyclophosphamide-based therapy
- Consider adding pneumocystis jiroveci pneumonia (PJP) prophylaxis for patients receiving bendamustine/rituximab or cladribine/cyclophosphamide/rituximab

Symptomatic Hyperviscosity:

- Plasmapheresis should be used as adjunctive therapy

GI Prophylaxis:

- Patients receiving steroids should receive prophylaxis with a proton pump inhibitor or H_2-receptor antagonist

[1] Refer to CDC vaccine schedules

Waldenstrom's Macroglobulinemia

APPENDIX B: Response Criteria for Waldenstrom's Macroglobulinemia

Standard IWWM Criteria	Response Criteria
Complete response	• IgM in normal range, **and** disappearance of monoclonal protein by immunofixation • No histologic evidence of bone marrow involvement and resolution of any adenopathy/organomegaly, if present at baseline, along with no signs or symptoms attributable to Waldenstrom's macroglobulinemia (WM) • Reconfirmation of the complete response status is required by repeat immunofixation studies
Very good partial response	≥ 90% reduction of serum IgM and decreases in adenopathy/organomegaly, if present at baseline, on physical examination or on CT[1] scan **and** no new symptoms or signs of active disease
Partial response	≥ 50% reduction of serum IgM and decrease in adenopathy/organomegaly, if present at baseline, on physical examination or on CT[1] scan **and** no new symptoms or signs of active disease
Minor response	≥ 25% but < 50% reduction of serum IgM and no new symptoms or signs of active disease
Stable disease	< 25% reduction **and** < 25% increase of serum IgM without progression of adenopathy/organomegaly, cytopenias, or clinically significant symptoms due to disease and/or signs of WM
Progressive disease[2]	Any one or more of the following criteria: • ≥ 25% increase in serum IgM by protein confirmed by a second measurement **or** progression of clinically significant findings due to disease (*i.e.*, anemia, thrombocytopenia, leukopenia, bulky adenopathy/organomegaly) • Symptoms (unexplained recurrent fever ≥ 38.4°C, drenching night sweats, ≥ 10% body weight loss, hyperviscosity, neuropathy, symptomatic cryoglobulinemia or amyloid) attributable to WM

IWWM = International Workshop on Waldenstrom's macroglobulinemia
[1] CT scan may include chest, abdomen, and pelvis with contrast
[2] Requires two consecutive assessments made at any time before the institution of any new therapy

SUGGESTED READINGS

The following is not meant to be a comprehensive list of available effective treatments for Waldenstrom's macroglobulinemia (WM); WM treatments are changing rapidly and new treatments and added information regarding previous treatments are available frequently. As a result updates should be taken into consideration and for similar reasons regimens reported only by abstract have been included on this reference list.

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DEVELOPMENT CREDITS

This practice algorithm is based on majority expert opinion of the Myeloma Center providers 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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