Hairy Cell Leukemia Treatment (PDQ®)–Health Professional Version

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General Information About Hairy Cell Leukemia

Incidence and Mortality

Hairy cell leukemia is an indolent, low-grade, B-cell lymphoid malignancy. It is rare, with only 1,200 to 1,300 new cases annually in the United States.[1]

Clinical Presentation

Hairy cell leukemia usually presents with:

- Splenomegaly.
- Varying degrees of leukopenia (occasionally leukocytosis).
- Pancytopenia.
- Monocytopenia.
- Bone marrow infiltration by atypical cells with prominent cytoplasmic projections (i.e., hairy cells).

Lymphadenopathy is absent, except with multiply recurrent progressive disease.

Diagnostic Evaluation

The following tests and procedures may be used to diagnose hairy cell leukemia:

- Flow cytometry.
- Bone marrow aspiration and biopsy.
- Immunophenotyping.
- Cytogenetic analysis.
- *BRAF* gene testing.
- Computed tomography scan.

The bone marrow is usually fibrotic and is not easily aspirated. It has circulating B cells with cytoplasmic projections (hairy appearance). Although a bone marrow biopsy may be required to enroll in a clinical trial, the hairy cell leukemia diagnosis can usually be made by flow cytometry.

In addition to the B-cell antigens CD19, CD20 (very high levels), and CD22, the cells coexpress CD11c, CD25, and CD103. The *BRAF* V600E pathogenic variant is a hairy cell leukemia–defining genetic feature

that can aid in diagnosis.[2,3]

There is a variation of hairy cell leukemia (HCL-v) which accounts for 10% of cases. HCL-v is distinguished clinically by an elevated white blood cell count (15–50 × 10^9/L) and aberrant markers, including variable (instead of bright) CD103 and the absence of CD23, CD25, CD12, and CD43.[4,5] HCL-v cells also lack *BRAF* variants. Patients with HCL-v have more aggressive clinical courses, reduced responses to purine nucleoside analogue-based therapy, and shorter durations of response.[5]

The depth of a complete remission can be evaluated with measurable residual disease (MRD) by testing for a *BRAF* variant or an immunoglobulin heavy chain gene rearrangement. However, the usefulness of altering therapeutic choices with MRD remains unclear and requires further evaluation.[6]

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Stage Information for Hairy Cell Leukemia

There is no generally accepted staging system used in the prognosis and treatment of hairy cell leukemia.

Treatment of Hairy Cell Leukemia

Hairy cell leukemia is highly treatable but rarely cured. Because it is easily controlled, many patients have prolonged survival with the use of sequential therapies. The decision to treat is based on signs of disease progression, including any of the following factors:

- Cytopenias (especially if symptomatic).

- Increasing splenomegaly.
- The presence of other, usually infectious, complications.

If the patient is asymptomatic and if blood counts are maintained in an acceptable range, therapy may not be needed.[1]

Treatment Options for Hairy Cell Leukemia

Prior to the COVID-19 (SARS-CoV-2) pandemic, the standard initial therapy for patients with hairy cell leukemia was infusion of cladribine daily for 5 days, given with or without eight weekly doses of rituximab.[2-4] However, treatment with a purine analogue–based regimen led to significant and prolonged neutropenia and impairment of T-cell function, which were both problematic during the pandemic in fighting viral infection and establishing vaccination-induced immunity.

Other options for initial standard therapy, instead of cladribine or pentostatin, may offer less toxicity in terms of infection and long-term risk of secondary malignancies. However, these options may provide less durable response.

The Hairy Cell Leukemia Foundation convened a virtual meeting of 39 experts from around the world to amend the 2017 consensus recommendations.[5] The adapted treatment guidelines, published in 2021, are based primarily on anecdotal experience and expert opinion, as controlled trials for this indolent leukemia cannot be completed expeditiously given the low incidence of this disease.[6][Level of evidence C3] The adapted treatment guidelines are summarized below.

1. Consider watchful waiting when feasible; asymptomatic patients with noncritical levels of pancytopenia can be monitored closely.
2. Cladribine, with or without rituximab,[4] remains the standard of care. However, due to the risk of serious and prolonged immunosuppression, nonchemotherapy treatment options may be preferable for older, frail patients with higher risk of infection (or for those who have active infections).
3. BRAF inhibitors such as vemurafenib, dabrafenib, or encorafenib are nonchemotherapeutic options that can be combined with rituximab or obinutuzumab.[7-10] Most patients with hairy cell leukemia have *BRAF* pathogenic variants, but this should be verified by flow cytometry. Despite extensive experience with vemurafenib for patients with relapsed disease, the U.S. Food and Drug Administration (FDA) has not approved oral vemurafenib for patients with hairy cell leukemia.
4. Consider using rituximab alone intravenously (IV) for 4 to 8 weeks or in combination with a BRAF inhibitor.[11] Anti-CD20 monoclonal antibodies can impair future vaccine response, but they do not affect immunity from prior vaccination.
5. In patients with relapsed disease, the previously mentioned options are available, along with ibrutinib (the Bruton tyrosine kinase inhibitor).[12]

Treatment options for hairy cell leukemia include:

1. Watchful waiting, if feasible.
2. Cladribine with or without rituximab.

3. BRAF inhibitors (vemurafenib or dabrafenib) with or without rituximab or trametinib.
4. Rituximab.
5. Pentostatin.
6. Ibrutinib.
7. Re-treatment with cladribine or pentostatin.
8. Bendamustine with rituximab.
9. Splenectomy.
10. Interferon.

Cladribine with or without rituximab

Cladribine may be given with or without rituximab to treat hairy cell leukemia.

Evidence (cladribine with or without rituximab):

1. In a phase II study, 68 patients with previously untreated hairy cell leukemia were randomly assigned to receive cladribine (0.15 mg/kg IV) on days 1 to 5, with eight weekly doses of rituximab either concurrently (starting on day 1) or delayed (starting after 6 months of cladribine treatment) if still positive with measurable residual disease (MRD) testing.[4][Level of evidence C3]
    - With a median follow-up of 96 months, 94% of patients who received concurrent therapy were MRD-free, compared with 12% of patients who received delayed therapy.
    - Although patients who underwent concurrent therapy had more need for platelet transfusions, they demonstrated higher neutrophil and platelet counts after 1 month.
    - A retrospective case series reported a median progression-free survival (PFS) of 67 months in patients with relapsed disease who received a purine nucleoside analogue (usually cladribine) plus rituximab.[13][Level of evidence C2]
    - A retrospective case series of nine patients with a histologic variation of hairy cell leukemia (HCL-v) reported an 88% complete response rate and 3-year PFS rate of 42% (95% confidence interval [CI], 1%–84%) after treatment with a purine nucleoside analogue (usually cladribine) plus rituximab.[14][Level of evidence C2]
2. Cladribine was given by daily subcutaneous injections or by daily 2-hour IV infusions for 5 to 7 days.[5,15-17][Level of evidence C3] Purine analogues should be avoided in cases of active infection or moderate to severe hepatic or renal impairment.
    - The complete response rate was 50% to 80%.
    - The overall response rate was 85% to 95%.
3. A National Cancer Institute group C protocol of 979 patients treated with cladribine reported lower response rates (i.e., 50% complete remission rate, 37% partial remission rate) compared with other studies.[18] Responses were durable in patients treated with a short course of cladribine, and patients who had a relapse often responded to re-treatment with cladribine.[2,13,19]
4. A retrospective review included 83 patients, aged 40 years and younger.[2]

- The median time to first relapse was 54 months for all responders, and the median overall survival (OS) was 21 years from diagnosis.
- Cladribine may cause fever and immunosuppression; documented infection was found in 33% of treated patients.

In a retrospective study of patients with cladribine-associated neutropenic fever, filgrastim (G-CSF) did not reduce the percentage of febrile patients, number of febrile days, or frequency of hospital admissions to receive antibiotics.[3]

BRAF inhibitors (vemurafenib or dabrafenib) with or without rituximab or trametinib

BRAF V600E pathogenic variants are found in almost 100% of patients with classic-form hairy cell leukemia and almost never found in patients with other B-cell lymphomas and leukemias, including HCL-v.[20][Level of evidence C3] Vemurafenib or other BRAF inhibitors such as dabrafenib can be given with rituximab or obinutuzumab.[10,21] The FDA has not approved BRAF inhibitors for hairy cell leukemia, but they can be used off-label in clinical practice.[22]

Evidence (vemurafenib with or without rituximab):

1. Several multicenter studies evaluated vemurafenib, given orally alone for 4 months or orally for 2 months with rituximab infused in eight doses over 18 weeks, in patients with relapsed or refractory hairy cell leukemia.[7,8,10,23][Level of evidence C3]
    a. After a median follow-up of 23 to 40 months, for the 86 patients treated with vemurafenib alone, the following was reported in two studies:[7,8,23][Level of evidence C3]
        - The overall response rate was 86% to 98%.
        - The complete response rate was 33% to 38%.
        - The median treatment-free survival was 18 to 25 months.
        - Retreatment at relapse resulted in an 86% response rate, and the median relapse-free survival was 12.7 months in one of the trials, with a 40-month median follow-up.[23][Level of evidence C2]
    b. After a median follow-up of 37 months, for the 30 patients treated with vemurafenib plus rituximab, the following was reported:[10][Level of evidence C3]
        - The complete response rate was 87%.
        - The PFS rate was 78% at 37 months.
        - In patients who had a complete response, 65% had no MRD.

Evidence (dabrafenib plus trametinib):

1. In a phase II trial of patients with relapsed or refractory disease, 55 patients received dabrafenib and trametinib orally until their disease progressed, they experienced unacceptable toxicity, or death occurred.[24]
    - With a median follow-up of 43.2 months, the overall response rate was 89.0% (95% CI, 77.8%–95.9%), the complete response rate was 65.5%, the 2-year PFS rate was 94.5%, and

the 2-year OS rate was 95.5%.[24][Level of evidence C1]

Rituximab

Rituximab can induce durable remissions (with minimal toxic effects), but rarely complete remissions, in patients with multiple relapses or refractory disease after treatment with a purine analogue or interferon.[11,22,25][Level of evidence C3]

Pentostatin

Pentostatin given IV every other week for 3 to 6 months produced a 50% to 76% complete response rate and an 80% to 87% overall response rate.[26] Complete remissions were of substantial duration. Purine analogues should be avoided in cases of active infection or moderate to severe hepatic or renal impairment.

Evidence (pentostatin):

1. Two trials reported results on the 9-year median follow-up of patients treated with pentostatin.[27,28]
    - The relapse-free survival rates ranged from 56% to 67%.
    - Side effects included fever, immunosuppression, cytopenias, and renal dysfunction.
2. A randomized trial compared pentostatin to recombinant interferon alfa-2a.[26]
    - Pentostatin demonstrated higher response rates and more durable responses.

Ibrutinib

Ibrutinib, a tyrosine kinase inhibitor, has been studied in the treatment of hairy cell leukemia.

Evidence (ibrutinib):

1. In a phase II study, 37 patients with refractory hairy cell leukemia were treated with ibrutinib. The median follow-up was 42 months.[29][Level of evidence C3]
    - The response rate was 54%.
    - The estimated 36-month PFS rate was 73%.
    - The OS rate was 85%.

Re-treatment with cladribine or pentostatin

Patients with hairy cell leukemia who have a relapse after the first course of cladribine or pentostatin often respond well to re-treatment with the same or another purine analogue, especially if relapse occurs after several years.[13][Level of evidence C3]

Bendamustine with rituximab

Evidence (bendamustine with rituximab):

1. A phase II study evaluated 12 patients with relapsed or refractory disease, three of whom were negative for *BRAF* variants. Patients received the combination of bendamustine and rituximab.[30]

- The overall response rate was 100%, and the complete remission rate was 50%.[30][Level of evidence C3]

Splenectomy

Splenectomy plays a decreasing role in treating hairy cell leukemia because effective alternatives are available. Splenectomy will partially or completely normalize the peripheral blood in most patients with hairy cell leukemia.[31] After a splenectomy, there is usually little or no change in the bone marrow, and virtually all patients have progressive disease within 12 to 18 months.

Interferon

Interferon alfa is no longer available because production has been halted.[32] According to the Hairy Cell Leukemia Foundation, ropeginterferon alfa-2b-njft is the best available preparation, but it is not FDA approved for hairy cell leukemia.

Interferon is useful when treating hairy cell leukemia during pregnancy because it does not involve cytotoxic agents.

Current Clinical Trials

Use our advanced clinical trial search to find NCI-supported cancer clinical trials that are now enrolling patients. The search can be narrowed by location of the trial, type of treatment, name of the drug, and other criteria. General information about clinical trials is also available.

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Latest Updates to This Summary (02/21/2025)

The PDQ cancer information summaries are reviewed regularly and updated as new information becomes available. This section describes the latest changes made to this summary as of the date above.

General Information About Hairy Cell Leukemia

Added Falini et al. as reference 1.

Treatment of Hairy Cell Leukemia

Revised text to state that cladribine, with or without rituximab, remains the standard of care. However, due to the risk of serious and prolonged immunosuppression, nonchemotherapy treatment options may be preferable for older, frail patients with higher risks of infection (or for those who have active infections). BRAF inhibitors such as vemurafenib, dabrafenib, or encorafenib are nonchemotherapeutic options that can be combined with rituximab or obinutuzumab.

Revised the list of treatment options for hairy cell leukemia to include interferon.

Revised text to state that vemurafenib or other BRAF inhibitors such as dabrafenib can be given with rituximab or obinutuzumab (cited Park et al. as reference 21).

Added Interferon as a new subsection.

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About This PDQ Summary

Purpose of This Summary

This PDQ cancer information summary for health professionals provides comprehensive, peer-reviewed, evidence-based information about the treatment of hairy cell leukemia. It is intended as a resource to inform and assist clinicians in the care of their patients. It does not provide formal guidelines or recommendations for making health care decisions.

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The lead reviewer for Hairy Cell Leukemia Treatment is:

- Eric J. Seifter, MD (Johns Hopkins University)

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