Recommended Referral Timing for Cellular Therapy Treatment

A RESOURCE FOR PHYSICIANS
There are many types of immune effector cellular therapy being explored to fight cancer: CAR T cells, genetically and non-genetically-modified T cells, NK cells, and vaccines.

Dana-Farber Brigham Cancer Center offers all FDA-approved CAR T products as well as numerous clinical trials of CAR T and other cellular therapies. This guide provides recommended referral timing for commercial CAR T-cell therapies. We also encourage you to contact us to discuss the cellular therapy clinical trials that may be available for your patients.

**Commercial CAR T-Cell Therapy**

CAR T-cell therapy is FDA approved for some forms of non-Hodgkin lymphoma, multiple myeloma and adult and pediatric B-cell acute lymphoblastic leukemia.

**Aggressive Non-Hodgkin Lymphoma**

For diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma

**Eligibility Criteria:**

- Confirmed diagnosis of DLBCL, primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma, or transformed follicular lymphoma to DLBCL that has relapsed or not responded to at least two prior lines of systemic therapy, if the initial response to first-line therapy was longer than 12 months.
  
  - Patients with these diagnoses who do not achieve remission or relapse within 12 months of first-line therapy are eligible for CAR T as a second-line therapy.

- Patients with DLBCL that has relapsed or not responded to first line treatment and are not eligible for stem cell transplant are eligible for CAR T as a second-line therapy.

**Recommended Referral Timing**

Refer for evaluation at first relapse, before initiating salvage therapy.

**For mantle cell lymphoma**

**Eligibility Criteria:**

- Histologically confirmed diagnosis of mantle cell lymphoma that has either not responded to, or has relapsed after, first line therapy.

**Recommended Referral Timing**

Refer for evaluation at first relapse, preferably before initiating salvage therapy.
Select Indolent Lymphomas

For follicular lymphoma

Eligibility Criteria:

• Histologically confirmed diagnosis of follicular lymphoma that has relapsed or not responded after two prior lines of treatment.

• No history of malignancy expected to shorten one's life expectancy, other than lymphoma.

Recommended Referral Timing
Refer for evaluation at first relapse, preferably before initiating salvage therapy.

Multiple Myeloma

Eligibility Criteria:

• Confirmed diagnosis of multiple myeloma that has relapsed or not responded (refractory) after four or more prior lines of treatment.

• Prior therapy must have included a proteasome inhibitor, an immunomodulatory drug, and an anti-CD 38 monoclonal antibody.

Recommended Referral Timing
Refer for evaluation after 2 prior of lines of therapy for multiple myeloma or after treatment with a proteasome inhibitor, immunomodulatory agent, and an anti-CD38 monoclonal antibody.

B-Cell Acute Lymphoblastic Leukemia

Eligibility Criteria:

• Confirmed diagnosis of B-cell ALL that has either not responded or relapsed after one line of prior treatment.

• Adequate organ, cardiac, and pulmonary function (must meet established criteria/measures).

Recommended Referral Timing
Refer for evaluation when relapsed/refractory after initial therapy.

Note: Patients younger than 18 years are evaluated through our pediatric program, Dana-Farber/Boston Children's Cancer and Blood Disorders Center.
**Clinical Trials**

**CAR T-Cell Therapy**
Researchers are exploring ways to improve CAR T-cell therapies and extend it to other types of cancer. Our program offers several trials of CAR T for other types of blood cancers as well as new studies of CAR T in solid tumors. Trials are also exploring combining CAR T with other therapies, giving CAR T earlier in the treatment cycle, and minimizing side effects.

**Other Cellular Therapies**
Studies are also exploring other types of cellular therapies across a range of cancer types.
- Engineered T-cell receptor (eTCRs) therapy is currently in clinical trials for patients with myeloma or sarcoma, or cervical or head and neck cancers caused by infections by the human papilloma virus, HPV.
- Tumor Infiltrating Lymphocyte (T-IL) therapy is being evaluated for several solid tumors such as cervical and lung cancer.
- NK cell therapies for head and neck cancer and to address relapse after stem cell transplant.

Visit dana-farber.org/cartclinicaltrials for an up-to-date list of trials, eligibility criteria, and contact information.

**Refer a Patient**
To discuss or refer a patient, call 877-801-CART (2278) or email cartinquiries@dfci.harvard.edu.