POLICY NUMBER UM_1048	SUBJECT Campath™ (alemtuzumab)		DEPT/PROGRAM UM Dept.	PAGE 1 OF 4
DATE REVIEWED 10/05/11, 04/10/13, 07/10/14. 12/01/15, 12/19/16, 10/09/17, 09/04/18, 08/08/19	APPROVAL DATE August 14, 2019	EFFECTIVE DATE August 14, 2019	REVISION DATES (latest version listed last) 02/20/11, 10/05/11, 04/10/13, 07/24/14, 12/01/15, 10/11/17, 09/21/18, 08/14/19	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Oncology	

I. PURPOSE

To define and describe the accepted indications for Campath (alemtuzumab) usage in the treatment of cancer

II. DEFINITIONS

Campath (alemtuzumab): is a recombinant human IgG-derived monoclonal antibody that binds to antigen CD52 which is found on the surface of B and T lymphocytes, most monocytes, macrophages and NK cells, and certain granulocytes, but not hematopoietic stem cells. The proposed mechanism of action is antibody-dependent cellular-mediated lysis following cell surface binding of Campath (alemtuzumab) to the leukemic cells.

Campath (alemtuzumab) is indicated as a single agent for the treatment of B-cell chronic lymphocytic leukemia (B-CLL).

Alemtuzumab is no longer available commercially but is provided through the Campath Distribution Program free of charge.

III. POLICY

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

Inclusion Criteria: Campath (alemtuzumab) may be considered medically necessary when any of the following selection criteria is met:

1. **Chronic lymphocytic leukemia (CLL)**
    a. The member has a diagnosis of stage II-IV Chronic lymphocytic leukemia (CLL) or Small lymphocytic lymphoma **AND** Campath (alemtuzumab) is being used as **ONE** of the following:
        i. First-line therapy with del(17p)/TP53 mutation
        ii. Relapsed or refractory CLL as a single agent or in combination with rituximab in members with a short response.

2. **Mycosis fungoides (MF)/Sezary syndrome (SS)**
    a. The member has a diagnosis of stage III MF or SS AND
    b. The member is refractory to or progressive following skin-directed therapies (topical corticosteroids, carmustine, mechlorethamine hydrochloride, phototherapy, or total skin electron beam therapy) and interferon alfa.
3. **Peripheral T-cell lymphoma**
    a. Campath (alemtuzumab) is being used as second-line therapy for relapsed or refractory angioimmunoblastic T-cell lymphoma, peripheral T-cell lymphoma not otherwise specified, or anaplastic large cell lymphoma in noncandidates for high-dose therapy with autologous stem cell rescue.

Exclusion Criteria: Campath (alemtuzumab) is not considered medically necessary when any of the following selection criteria is met:

1. Member has an active systemic infection or underlying immunodeficiency (i.e. HIV) other than CLL induced immunodeficiency.
2. Member has autoimmune cytopenias or recurrent/persistent severe cytopenias.
3. Dosing exceeds single dose limit of Campath (alemtuzumab) 30 mg and cumulative weekly dose of 90 mg.
4. Maximum duration of therapy (including dose escalation) exceeds 12 weeks.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

IV. PROCEDURE

Requests for Campath (alemtuzumab) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. **Dosage and Administration**
    a. Initial dose: 3 mg administer as an IV infusion over 2 hours, or SQ, once daily (Not as IV push or bolus).
    b. Gradually escalate to the maximum recommended single dose of 30 mg as tolerated (infusion reactions should be grade 2 or less). Withhold alemtuzumab for grade 3 or 4 infusion reactions. Dose escalation to 30 mg can be done in 3-7 days in most members.
    c. Maintenance dose: 30 mg per day, 3 times per week on alternate days (i.e. Monday, Wednesday, Friday)
    d. Gradual dose escalation to the maintenance dosage is required at treatment initiation and after therapy interruption for 7 or more days.
    e. Single doses > 30 mg or cumulative weekly doses of > 90 mg should not be given because of an increased incidence of pancytopenia.
    f. Total duration of therapy, including dose escalation is 12 weeks.
    g. Do not administer live viral vaccines to member who have recently received Campath (alemtuzumab).

h. Administer prophylaxis against Pneumocystis jiroveci pneumonia (PCP) and herpes virus infection. Continue PCP and herpes viral prophylaxis for a minimum of 2 months after completion of Campath or until the CD4+ count is ≥ 200 cells/μL, whichever occurs later. Antifungals should also be considered.

2. Dose modifications for hematologic toxicities

a. ANC < 250/μL and/or platelet count ≤25,000/μL:

i. For first occurrence: Withhold Campath therapy. Resume Campath at 30 mg when ANC ≥ 500/μL and platelet count ≥ 50,000/μL

ii. For second occurrence: Withhold Campath therapy. Resume Campath at 10 mg when ANC ≥ 500/μL and platelet count ≥ 50,000/μL

iii. For third occurrence: Discontinue Campath therapy.

b. For ≥ 50% decrease from baseline in member initiating therapy with a baseline ANC ≤ 250/μL and/or a baseline platelet count ≤ 25,000/μL:

i. For first occurrence: Withhold Campath therapy. Resume Campath at 30 mg upon return to baseline value(s)

ii. For second occurrence: Withhold Campath therapy. Resume Campath at 10 mg upon return to baseline values(s)

iii. For third occurrence: Discontinue Campath therapy.

1. Withhold Campath during serious infection or other serious adverse reactions until resolution
2. Discontinue Campath for autoimmune anemia or autoimmune thrombocytopenia
3. There are no dose modifications recommended for lymphopenia.

3. Monitoring

a. Evidence of chemotherapeutic response
b. CBC, platelet counts; at least weekly
c. CD4+ counts; after treatment until recovery to 200 cells/microliter or greater
d. Signs/symptoms of Grade 3 or 4 infusion reactions
e. Signs/symptoms of immunosuppression and serious infections
f. Signs/symptoms of CMV infection during and for at least 2 months following treatment

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Campath prescribing information. Genzyme Corporation, Cambridge, MA. 2018.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.

3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2019.