LEMTRADA® (alemtuzumab) Healthcare Professional Checklist

Timing	Activity	Detail
Initial screening of patients	***Contraindications***	☐ Hypersensitivity to the active substance (alemtuzumab) or to any of the excipients: disodium phosphate dihydrate (E339), disodium edetate dehydrate, potassium chloride (E508),potassium dihydrogen phosphate (E340), polysorbate 80 (E433), sodium chloride, water for injections ☐ Human Immunodeficiency Virus (HIV) infection ☐ Patients with severe active infections until resolution
	Precautions for use	☐ Consider combined effects on the patient's immune system if LEMTRADA is used concomitantly with antineoplastic orimmunosuppressive therapies
	Recommended screening	☐ Evaluate for active and inactive ("latent") tuberculosis (per local guidelines) ☐ Consider screening patients at high risk of hepatitis B virus (HBV) and/or hepatitis C virus (HCV) infection. Exercise caution in prescribing LEMTRADA to patients identified as carriers of HBV and/or HCV ☐ Human Papillomavirus (HPV) screening recommended prior to treatment and annually after treatment
	Baseline tests	☐ Complete blood count with differential ☐ Serum creatinine levels ☐ Thyroid function tests, such as thyroid stimulating hormone (TSH) level ☐ Urinalysis with microscopy
	Understanding of benefits & risks	☐ The patient has been informed about and understands the risks of serious autoimmune disorders, infections and malignancies,and the measures to minimise risk (e.g. watching for symptoms,carrying the Patient Alert Card and the need to commit to periodic monitoring for 48 months after the last treatment)
6 weeks prior to treatment *(if needed)*	***Vaccinations***	☐ It is recommended that patients have completed local immunisation requirements ☐ Consider varicella Zoster virus vaccination of antibody negative patients before initiating a course of LEMTRADA treatment
For at least one month after treatment	***Diet***	☐ Recommend patients to start to avoid ingestion of uncooked or undercooked meats, soft cheeses and unpasteurized dairy products two weeks prior to, during, and for at least one month after treatment

LEMTRADA® alemtuzumab 12mg IV

Timing	Activity	Detail
Immediately prior to treatment	**Pretreatment** ***Pretreatment for infusion-associated reactions*** ***Oral prophylaxis for herpes***	□ Immediately prior to LEMTRADA administration, pretreat with corticosteroids on each of the first 3 days of any treatment course □ Pretreatment with antihistamines and/or antipyretics prior to LEMTRADA administration may also be considered □ Administer 200 mg aciclovir (or equivalent) twice a day from first day of treatment and continuing for a minimum of 1 month following treatment with LEMTRADA
	General health	□ Delay initiation of LEMTRADA administration in patients with active infection until the infection is fully controlled
	Pregnancy & contraception	□ Ensure women of child bearing potential use effective contraceptive measures when receiving a course of treatment with LEMTRADA and for 4 months following the course of treatment □ Perform pregnancy test. If the patient is pregnant, administer LEMTRADA only if the potential benefit justifies the potential risk to the foetus
At end of infusion	***Infusion***	□ Flush lines to insure the entire dosage has been administered to the patient
During treatment and for 48 months after last treatment	***Monitoring activities***	□ Complete blood count w/differential and serum creatinine: monthly until 48 months after last treatment □ Urinalysis with microscopy: monthly until 48 months after last treatment □ Thyroid function tests: every 3 months until 48 months after last treatment

_____ on __ __ __/__ __ __/__ __ __ __
(Insert patient's name) (Insert date)

_____ __ __ __ __/__ __ __/__ __ __ __
(Insert patient's medical record number) (Insert patient date of birth)

_____
(Prescriber's name)

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