PRESCRIBING CHECKLIST

LEMTRADA® alemtuzumab 12mg IV

This Checklist is part of the LEMTRADA® (alemtuzumab) risk management strategy and is to be used in conjunction with Lemtrada HCP Guide and Product Information

INITIAL SCREENING OF PATIENTS

Patient selection

- ☐ Patients with relapsing forms of multiple sclerosis (MS) with active disease as defined by clinical or imaging features
- ☐ Patient has been assessed as suitable for Lemtrada based on individual benefit versus risk
- ☐ Patient is able to commit to, and comply with, monitoring for 48 months after last infusion

Recommended screening#

- ☐ Tuberculosis
- ☐ Evaluate MRI scan for any sign suggestive of progressive multifocal leukoencephalopathy (PML) prior to initiation, and re-administration, of Lemtrada
- ☐ HIV
- ☐ Hepatitis B and C (Including Hep B Core antibodies)
- ☐ Varicella Zoster (VZV-IgG)
- ☐ Human papillomavirus
- ☐ Pregnancy
- ☐ Consider evaluation of cytomegalovirus (CMV) immune serostatus

Full details available in Lemtrada HCP Guide

Contraindications

- ☐ Patients with known hypersensitivity or anaphylactic reactions to alemtuzumab, to murine proteins or to any of the excipients
- ☐ Patients with human immunodeficiency virus (HIV)
- ☐ Patients with severe active infections, until resolved
- ☐ Uncontrolled hypertension
- ☐ History of arterial dissection of the cervicocephalic arteries
- ☐ History of stroke
- ☐ History of angina pectoris or myocardial infarction
- ☐ Known coagulopathy, on anti-platelet or anti-coagulant therapy

Other considerations

- ☐ Delay initiation of Lemtrada administration in patients with severe active infection until resolution
- ☐ Recent Immunosuppression
  - Potential risk of immunosuppression should be taken into account when considering administration of LEMTRADA with, or after, immunosuppressive.
- ☐ Review patient's immunisation status (Vaccinations must be completed at least 6 weeks prior to initiation of treatment)

Lemtrada is not recommended for patients with inactive disease or those stable on current therapy.

PRIOR TO TREATMENT

Baseline test

- ☐ Obtain baseline electrocardiogram (ECG) vital signs, including heart rate and blood pressure (BP) measurements
- ☐ Full blood count
- ☐ Serum transaminases and serum creatinine
- ☐ Urinalysis with cell count and protein estimate
- ☐ Thyroid function test e.g. TSH

Vaccinations

- ☐ It is recommended that patients immunisation schedule is up to date at least 6 weeks prior to treatment
- ☐ Consider VZV vaccination of antibody negative patients, at least 6 weeks prior to treatment

Other considerations

- ☐ Provide patient with Lemtrada Patient Guide and Patient Alert Card
- ☐ Ensure the patient has been informed about, and understands, the potential safety events associated with Lemtrada (including serious autoimmune disorders, infection and malignancies) and the measures to minimise risk (eg watching for symptoms, carrying the Patient Alert Card and the need to commit to monthly monitoring for 48 months after last infusion)
- ☐ Women of child bearing potential should use effective contraceptive measures when receiving a course of treatment with Lemtrada and for 4 months following the course of treatment

INFUSION ADMINISTRATION

Pregnancy/breastfeeding

☐ Lemtrada is not recommended in patients who are currently pregnant or breastfeeding

Premedication/prophylaxis

☐ Oral prophylaxis for herpes (acyclovir 200 mg BID or equivalent) from first day of treatment and continuing for a minimum of 1 month following treatment

☐ Methylprednisolone 1 g I.V. immediately prior to Lemtrada administration continuing for the first 3 days of any treatment course

☐ Pretreatment with antihistamines and/or antipyretics prior to Lemtrada administration may also be considered

Pre-infusion evaluations

☐ Obtain a baseline ECG and vital signs, including heart rate and BP measurements

☐ Perform laboratory tests (full blood count with differential, serum transaminases, serum creatinine, thyroid function test and urinalysis with microscopy)

During infusion

☐ Monitor heart rate, BP, and overall clinical status of the patient at least once every hour

☐ Discontinue the infusion:

- in case of a severe adverse event
- if the patient shows clinical symptoms suggesting development of a serious adverse event associated with the infusion (myocardial ischaemia, haemorrhagic stroke, cervicocephalic arterial dissection or pulmonary alveolar haemorrhage

☐ Observation for infusion reaction is recommended during, and for 2 hours after, each Lemtrada infusion

Post-infusion

☐ Flush lines to ensure the entire dosage has been administered to the patient

☐ Observe patients for a minimum of 2 hours after each infusion. Patients displaying clinical symptoms that may indicate a serious adverse event should be closely monitored until complete resolution of the symptoms and observation time extended, as appropriate

☐ Educate patients about the potential for a delayed onset of infusion-associated reactions and instruct them to report symptoms immediately, and seek appropriate medical care, if they arise

AFTER EACH TREATMENT COURSE

Patient reminder

- ☐ Ensure that the patient's monthly/quarterly monitoring has been organised
- ☐ Remind the patient about the serious risks associated with Lemtrada and ensure the patient understands the need to commit to monitoring for 48 months after last infusion
- ☐ Remind the patient to remain vigilant for symptoms related to autoimmune conditions and to seek medical help if they have any concerns (Refer to Lemtrada Patient Guide for information regarding signs and symptoms)
- ☐ For at least one month after each treatment, patients should avoid or adequately heat foods that are potential sources of *Listeria monocytogenes*

Monitoring

All tests to continue for 48 months after last infusion

Monthly

- ☐ FBC
- ☐ Serum creatinine
- ☐ Urinalysis
- ☐ Serum transaminases

3 Monthly

- ☐ Thyroid function test e.g. TSH

Annually

- ☐ HPV Screening

PLEASE REVIEW FULL PRODUCT INFORMATION BEFORE PRESCRIBING. FULL PRODUCT INFORMATION IS AVAILABLE FROM SANOFI AUSTRALIA ON 1800 818 806 OR https://qr.medsinfo.com.au/tx/sw.cfm?h=swclemtr

For Medical Information and Adverse Event reporting please call 1800 818 806

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