Nurse List of Duties relating to Disease Modifying Therapies

Background

The pathology of multiple sclerosis (MS) [1]includes inflammatory and neurodegenerative mechanisms or impacts on the central nervous system (CNS). These mechanisms underly disease progression, relapses and eventually disability acquisition. Improved use of updated diagnostic criteria and early diagnosis of multiple sclerosis and effective treatment of the disease has notably led to improved patient outcomes. [23]

Disease Modifying Therapies (DMTs) are one of the cornerstones for effective disease management in multiple sclerosis. There are currently a range of DMTs approved for use in Australia[4] with varying degrees of efficacy for reducing the risk of relapses, increased lesions on the CNS and preserving neurological function and brain reserves. Available DMTs vary in the route and frequency of delivery, tolerability and treatment adherence, adverse effects, risks of toxicity, use during or before potential pregnancy and other related risks. Patients are faced with a plethora of treatment decisions post-diagnosis. The efficacy and treatment adherence relies on effective diagnosis acceptance and matching of individual patients with the most appropriate risk-benefit profile DMTs available. As such, it is necessary to establish logical and safe treatment protocols, for each patient on the respective therapies.

The MS nurse role primarily involves immunotherapy support, enhancing patient confidence in their ability to start and adhere to current treatments, which aim to alter the disease course of multiple sclerosis. The MS nurse provides education, monitoring and support during and beyond the therapy initiation period, to increase the likelihood of patients adhering to long-term therapy. A crucial aspect of this role is to support long-term, treatment-specific vigilance programs, to enable patient monitoring for potential side effects and safety concerns[5].

Tysabri Nurse List of Duties

- Utilise Tysabri 'workup' checklist to screen patients for suitability for Lemtrada commencement – e.g. review pre-screening blood tests; ensure recent Magnetic resonance imaging (MRI) took place; ensure patient has signed Tysabri consent; identify likely barriers to compliance with long-term post-treatment monitoring requirements.
- Counsel and educate patients about Tysabri as per workup checklist – including mode of action; likely efficacy; short and long-term risks and side-effects; importance of follow-up blood tests at Week 3 and Month 3; family planning considerations; pap smears and vaccinations.
- Coordinate repeat Nurse-led clinic visits as required, to ensure patients are informed and ready for Tysabri treatment.
- Liaise with GP regarding commencement of Lemtrada & need for vaccinations/pap smear.
- Liaise with Treatment Centre to book patients in for initial treatment.
- Liaise with Treatment Centre to ensure patients are attending regularly for treatment every 4 weeks.

- Contact patient if they are not adhering to 4-weekly schedule to identify issues and barriers; report these to clinical team.
- Liaise with accommodation provider as required to book patients in for accommodation.
- Coordinate paperwork for Treatment Centre: referral and drug chart.
- Maintain database with current information including start date of Tysabri; MRI dates; John Cunningham Virum (JCV) testing.
- Send patient initial Tysabri letter and initial pathology testing, due at 3 weeks and 3 months.
- Ensure patient is booked into clinic in accordance with Therapeutic Good Administration (TGA) requirement for Neurology review: 3 months post first infusion, then 6-monthly.
- Review post-Tysabri blood test at 3 weeks to identify possible liver function test (LFT) derangement prior to second infusion.
- Respond to Treatment Centre enquiries and issues as they arise.
- Actively participate in discussions about clinical issue management with neurology team.
- Ensure subsequent MRIs are performed as per vigilance program.
- Ensure subsequent JCV testing is maintained as per vigilance program.
- Maintain accurate record of Tysabri patients - those treated, underway, pending treatment and possible candidates.
- Assist in the reporting of any adverse reactions.

Lemtrada Nurse List of Duties

- Participate in weekly Roundtable multidisciplinary meeting to identify potential Lemtrada candidates and provide nursing expertise, counselling, education and support to patients.
- Attend weekly Neuroimmunology clinic to provide immunotherapy education and counselling.
- Attend weekly Nurse-led clinic to provide immunotherapy education and counselling.
- Advise patients about immunotherapy treatment options; coordinating and providing instruction in the initiation of prescribed treatments.
- Utilise Lemtrada workup checklist (attached) to screen patients for suitability for Lemtrada commencement e.g. review pre-screening blood and urine tests; identify likely barriers to compliance with long-term post-treatment monitoring requirements.
- Counsel and educate patients about Lemtrada as per workup checklist (attached) – including mode of action; likely efficacy; short and long-term risks and side-effects; importance of ongoing monthly blood/urine monitoring for 48 months post treatment; family planning considerations; dietary advice; pap smears and vaccinations.

- Coordinate repeat Nurse-led clinic visits as required, to ensure patients are informed and ready for Lemtrada treatment.
- Liaise with GP regarding commencement of Lemtrada & need for vaccinations/pap smear.
- Liaise with Treatment Centre to book patients in for treatment (5 days year 1; 3 days year 2).
- Liaise with accommodation provider as required to book patients into accommodation.
- Coordinate referral to Treatment Centre; drug chart; IV orders; Lemtrada script; premedication script.
- Liaise with Pharmacy re Lemtrada supplies.
- Register patients to Bloodwatch program.
- Supply patients with monthly Bloodwatch pathology request forms.
- Oversee alerts in relation to the Bloodwatch program (received by email and/or SMS).
- Respond to Treatment Centre enquiries and issues as they arise.
- Actively participate in discussion with neurology team regarding management of clinical issues.
- Coordinate follow-up clinic appointments.
- Ensure subsequent MRIs are performed as per vigilance program.
- Maintain accurate record of Lemtrada patients - those treated, underway, pending treatment and possible candidates.
- Ensure all Lemtrada patients are monitored in accordance with the Lemtrada vigilance program (e.g. MRI, clinic appointments, blood/urine tests).
- Assist in the reporting of any adverse reactions.

Gilenya Nurse List of Duties

- Utilise Gilenya workup checklist to screen patients for suitability for Lemtrada commencement – e.g. review pre-screening blood tests; ensure recent Electrocardiogram (ECG) has been performed; ensure pre-Gilenya ophthalmic review to screen for risk factors for macular oedema has been performed; identify likely barriers to compliance with long-term post-treatment monitoring requirements.
- Counsel and educate patients about Gilenya as per workup checklist – including mode of action; likely efficacy; short and long-term risks and side-effects; importance of follow-up blood tests at Week 2, Week 4 and Month 3; importance of follow-up ophthalmic assessment at 3 months and annually; family planning considerations; pap smears and vaccinations.
- Coordinate repeat Nurse-led clinic visits as required, to ensure patients are informed and ready for Gilenya treatment.

- Liaise with GP regarding commencement of Gilenya & need for vaccinations/pap smear.
- Liaise with Treatment Centre to book patients in for first-dose or for subsequent re-dosing following treatment interruption
- Contact patient if they are not adhering to treatment to identify issues and barriers; report these to clinical team.
- Coordinate referral for Treatment Centre.
- Coordinate script for patient.
- Ensure database is maintained with current information including start date of Gilenya; follow-up appointments and ophthalmic assessment.
- Send patient initial a) Gilenya letter and b) initial pathology testing due at 2 weeks, 4 weeks and 3 months.
- Review post-Tysabri blood tests to identify significant lymphopaenia and other issues.
- Ensure patient is booked into clinic in accordance with Gilenya vigilance program: 3 months post first dose, then 3 to 6 monthly.
- Respond to Treatment Centre enquiries and issues as they arise.
- Actively participate in discussion with neurology team regarding management of clinical issues.
- Maintain accurate record of Gilenya patients - those treated, underway, pending treatment and possible candidates.
- Assist in the reporting of any adverse reactions

Mavenclad Nurse List of Duties

- Utilise *Criteria for Starting and Continuing Therapy, Special Warnings and Precautions for Use and Contraindications sheet* to screen patients for suitability for Mavenclad commencement – including screening for latent infections (especially tuberculosis and hepatitis B and C), active chronic and acute infections (i.e. HIV); lymphocyte counts; patients with active malignancy, hypersensitivity to cladribine/fructose intolerance; those who might be immunocompromised and patients with moderate or severe renal impairment. Mavenclad is contraindicated during pregnancy and breastfeeding.
- If the patient has not had a recent Magnetic Resonance Imaging (MRI), ensure a baseline MRI has been arranged. If patient is switching from another MS agent, check risks of Progressive multifocal leukoencephalopathy (PML).
- Counsel and educate patients about Mavenclad as per workup checklist – including mode of action, likely efficacy, short and long-term risks and side-effects; vaccination prior to commencement (if needed) and the importance of follow-up blood tests i.e. haematology parameters monitoring at 2 and 6 months after starting treatment in each treatment year.

- Female patients using systemically-acting hormonal contraceptives should be counselled to add a barrier method for at least 4 weeks after the last dose, in each treatment year.
- Liaise with GP regarding commencement of Mavenclad and need for vaccinations. Patients with no history of exposure to varicella zoster virus (VZV) should receive particular attention.
- Advise patient's GP of need for irradiated blood products following administration of Mavenclad.
- Advise patients of need for annual GP review for routine health check, including skin/breast/prostate/pelvic assessment.
- Coordinate repeat Nurse-led clinic visits as required to ensure patients are informed and ready for Mavenclad treatment.
- Ensure database is maintained with current information including start date of Mavenclad; follow-up appointments.
- Inform patient of potential side effects and contact details in case of any concerns. Send patient a) initial Mavenclad letter and b)initial pathology testing.
- Review post-blood tests to identify significant issues relating to i.e. lymphopenia.
- Ensure patient is booked into clinic in accordance with protocol.
- Actively participate in discussion with neurology team regarding management of clinical issues.
- Maintain accurate record of Mavenclad patients - those treated, underway, pending treatment and possible candidates.
- Assist in the reporting of any adverse events.

References

[1] Huang, W.J., Chen, W.W.. & Zhang, X. (2017). Multiple sclerosis: Pathology, diagnosis and treatments. *Exp Ther Med*; 13(6):3163–3166.

2 Giovannoni, G., Butzkueven, H., Dhib-Jalbut, S., Hobart, J., Kobelt, G., Pepper, G., Sormani, M.P., Thalheim, C. , Traboulsee, A. & Vollmer, T. (2016). Brain health: time matters in multiple sclerosis. *Mult Scler Relat Disord*, 2016 Sep; 9 Suppl 1:S5-S48..

[3] Kanavos, P., Tinelli, M., Efthymiadou, O., Visintin, E., Grimaccia, F. & Mossman J (2016). *Towards better outcomes in multiple sclerosis by addressing policy change* - The International MultiPlE Sclerosis Study (IMPrESS)., March 2016 report. Retrieved from: http://eprints.lse.ac.uk/66219/1/Kanavos_IMPRESS-Report-March-2016.pdf

[4] MS Australia (2023). *Treatments.* Retrieved from: https://www.msaustralia.org.au/treatments/

[5] MS Australia, Menzies Institute for Medical Research & MS Nurses Australasia Inc (2022). *MS Nurse Care in Australia: Patterns of access and impact on health outcomes*. Retrieved from: https://www.msaustralia.org.au/about-us/reports-and-financials/