Establishing a Gilyena Service in Greater Manchester (UK).

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Introduction
Within the UK there has been limited access to Gilyena due to the wait for guidance from the National Institute of Clinical Excellence (NICE). However, The Greater Manchester Neurosciences Medicines Management Sub-group of the GMWMMG and the GM Neurosciences Network Board considered the use of fingolimod based on a sub-group of patients with multiple sclerosis: (See below).

- Patients who have rapidly evolving severe (RES) MS but are not considered suitable for natalizumab (Tysabri) because of the clinical concerns (risk stratification) about the possibility of developing progressive multifocal leukoencephalopathy (PML)
- Patients who fail on natalizumab due to neutralising antibodies and, or, anaphylactic reaction
- Patients who fail on natalizumab due to relapses.
- Patients who fail on a beta-interferon (Avonex, Betaferon/Extavia, Rebif 22/44) and/or glatiramer acetate (Copaxone) due to inability to self-inject, lack of adequate injection sites or skin necrosis.
- Patients who develop high and sustained levels of neutralising antibodies to a beta-interferon (Avonex, Betaferon/Extavia or Rebif 22/44) and also fail on glatiramer acetate (Copaxone) due to inability to self-inject, lack of adequate injection sites or skin necrosis.

This has allowed for diversity of the traditional MS Clinical Nurse Specialist (CNS) to develop a nurse led service for this group of patients.

Methods
Original trial protocols were adapted for clinical use; specific clinics were identified in order to “fast track” potential patients. Initial time scale from patient identification to commencement of treatment was 6 weeks (pre European Medicines agency [EMA] recommendations).

Lead nurse for Gilyena responsibilities:
Coordination of all aspects of screening and results pre treatment; individual patient funding application; coordination of admission onto neurology day unit and initiating first dose; subsequent monitoring during the initial 6 hours; nurse led follow up clinics at month 1, 3, 6 and 9. Priority contact number for patients on Gilyena to access advice rapidly if needed.

Below is the current status re patients identified as suitable for Gilyena:

Current Situation:
Due to EMA recommendations, the level of cardiovascular monitoring has increased following 11 unexplained sudden deaths that may be cardiac in nature (Feb 2012). The Gilyena service has now developed into a collaboration between the MS team and Cardiologists at SRFT. Whilst this has resulted in a delay in starting patients onto treatment it has led to a greater examination of evidence available in order to further develop protocols that reflect best and safe practice. This will further enhance the nurses pivotal role in coordinating and caring for this group of patients.

Ratification of the latest protocol is awaited in order to proceed to treatment for identified patients.

References:
www.gmneurosciences.nhs.uk/Summary%20Fingolimod%Final%202014-9-11.pdf