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| **Monitoring and prescribing arrangements for**  **Sub-cutaneous Methotrexate** |  |

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| **Background** | Methotrexate is a cytotoxic folic acid antagonist used to treat chronic inflammatory conditions and certain cancers. It inhibits the enzyme dihydrofolate reductase and inhibits synthesis of DNA, RNA and proteins.  Methotrexate is licensed for the treatment of certain cancers, as well as some chronic inflammatory disorders. It is not licensed for all the conditions it is used to treat. However, its use for the indications below are well established and supported by clinical specialists.  This agreement does not cover treatment of cancer, or treatment of people under the age of 18 years. |
| **Indication** | The licensed indications for methotrexate include:   * Active rheumatoid arthritis * Severe psoriasis * Severe psoriatic arthritis   Licensed indications vary with brand.  See relevant [summary of product characteristics](https://www.medicines.org.uk/emc/search?q=methotrexate) for full details.  This arrangement also includes treatment of chronic inflammatory conditions where off-label use of methotrexate is appropriate, including, but not limited to, the following specialities and conditions:   * Rheumatology (e.g. inflammatory arthritis, connective tissue disease, vasculitis) * Dermatology (e.g., severe eczema, bullous conditions)   It is appreciated that sub-cutaneous methotrexate is used in gastroenterology services, but this arrangement is only relevant to dermatology and rheumatology patients as these are the patients who are most likely to require long term management with the sub-cutaneous preparation |
| **Clinical monitoring** | |  |  | | --- | --- | | **Monitoring** | **Frequency** | | * Full Blood Count (FBC) * Urea & Electrolytes (U&Es) including creatinine * Alanine Transaminase (ALT)Aspartate transferase(AST) and albumin * Rheumatology patients: C-Reactive Protein (CRP) &/or Eosinophil sedimentation rate (ESR); specialist to confirm * Psoriasis patients: serum Procollagen III N-terminal peptide (PIIINP) | At least every 12 weeks, and more frequently in patients at higher risk of toxicity, as advised by the specialist team.  **The exact frequency of monitoring to be communicated by the specialist in all cases**. | |
| **Specialist’s Responsibilities** | * **Prescribing of sub- cutaneous methotrexate remains the responsibility of the specialist team throughout the patient’s treatment**. This includes   + Initial prescribing through the medical day unit(s) until stable   + Prescribing via homecare prescriptions in line with Trust policy * **The initial phlebotomy service** ( taking of patients’ bloods) in line with agreed monitoring schedule until responsibility transferred to GP ( usually after THREE months) * **Monitoring of the blood test results remains the responsibility of the specialist team throughout the patients treatment** * Training of the patient to enable self- administration of sub-cutaneous methotrexate * Ensuring that the patient is aware of their responsibilities to attend regular phlebotomy appointments at their GP practice. Also outline consequences, i.e. no further supplies of medication will be authorised without appropriate blood results being available * Provide phlebotomy form(s) , completed and with the date that an appointment for a blood test at their GP practice is required, to enable blood monitoring * Contacting patients when there are no phlebotomy results available to review, i.e. those who fail to attend GP practice. * Prescribing of folic acid - Patients should be prescribed folic acid 5mg, usually ONCE weekly, to be taken preferably the day after methotrexate. In some cases the specialist may decide that a different dose of folic acid is required. Folic acid should not be taken on the same day as methotrexate   Transfer of the responsibility for the phlebotomy service ( taking of bloods) to primary care is normally after the patient has been treated for THREE months, the dose has been optimised, and with satisfactory investigation results for at least FOUR weeks |
| **GP’s Responsibilities** | * Accepting or rejecting request to enter into this shared monitoring agreement with the specialist team within 28 days, if rejecting please state concerns and reasons. * Making appointments for routine phlebotomy services (taking of patients’ bloods) in line with agreed dates on blood forms supplied to patient by the specialist team * Ensure that the blood test results are accessible to the specialist team via ICE * Vaccinations - Offering the following vaccinations, in line with national guidance and the green book.   + Shingles vaccination: one-off.   + Influenza vaccination: annual |
| **Patients Responsibilities** | * Arranging appointment(s) at GP practice for routine phlebotomy services, in line with blood request forms supplied by specialist * Holding on to their completed phlebotomy form(s) until they are required * Attending appointments at their GP practice, ensuring the completed phlebotomy form is taken along, to have their blood monitoring |
| **Contact Details** | Thank you for agreeing to support the monitoring of this patient by carrying out the necessary phlebotomy services to enable secondary car specialist teams to carry out therapeutic drug monitoring, which in turn enables safe and appropriate prescribing. If you have any concerns or queries, please contact the Consultant, secretary or call the appropriate helpline below  UHND Rheumatology Helpline: 0191 3332763  DMH Rheumatology Helpline: 01325 743881  There is no dedicated dermatology So contact should be made with the individual consultant or specialist non-medical prescriber. |