NHS
Barnet
Clinical Commissioning Group

SERVICES SPECIFICATION

Locally Commissioned Service Number	LCS 2015/16 – 006(S)
Service Name	Methotrexate Monitoring
Barnet CCG Responsible Directorate	Care Closer to Home
Accountable Budget	Primary Care Budget
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Provider organization/s	GP practice member of NHS Barnet CCG
Period	1st April 2019 – 31th March 2020
Date of Review	April 2020

1. Population Needs

1.1 National/local context and evidence base

The treatment of several diseases within the field of medicine is increasingly reliant on drugs that, while clinically effective, need regular blood monitoring. This is due to the potentially serious side effects that these drugs can occasionally cause. It has been shown that the incidence of side effects can be reduced significantly if this monitoring is carried out in a well-organised way, close to the patient's home. Approximately 6% of hospital admissions are due to adverse drug reactions (ADRs)[1], and 3.7% are drug related and preventable[2]. Half of these admissions are caused by three groups of drugs which are among the most commonly prescribed, namely warfarin and other anticoagulants, non-steroidal anti-inflammatory drugs (NSAIDs) and anti-platelets, and diuretics and other renal toxic drugs[2]. Since they are much less commonly prescribed, cytotoxic drugs, like methotrexate, leflunomide and azathioprine, do not cause emergency hospital admission on the same scale. However, their inherent toxicity means that they do regularly cause severe harm, including death (although this is rare), and have been the subject of regular National Patient Safety Agency (NPSA) alerts as a consequence[3]. Practices need to ensure that prescriptions for community cytotoxic drugs are appropriate and carefully monitored to minimise risk. Current data drawing on work in progress that indicates the prescribing and monitoring of community cytotoxic is suboptimal and potentially unsafe.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	✓
Domain 2	**Enhancing quality of life for people with long-term conditions**	✓
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	✓
Domain 4	**Ensuring people have a positive experience of care**	✓
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	✓

[1] Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ 2004;329(7456): 15-9.
[2] Howard RL, Avery A, Slavenburg S, Royal S, Pipe G, Lucassen P, et al. Which drugs cause preventable admissions to hospital? A systematic review. British Journal of Clinical Pharmacology 2007;63(2):136-47.
[3] NPSA. Actions that can make anticoagulant therapy safer. Birmingham: National Patient Safety Agency, 2007.

2.2 Local defined outcomes

As outlined in table below;

Baseline Performance Targets				
Quality and Performance Indicators				
Activity	***Key performance Indicator***	***Target***	***Method of measurement***	***Frequency of/ reporting timescale***
Audit Requirements	Practices are required to complete the annual audit form around the following; % of patients prescribed Methotrexate and were not READ coded onto register.	0-10%	Provider information returns	Annual
Audit Requirements	% of patients on Methotrexate who have their dose prescribed on prescription (in mg and number of tablets and NOT "prn")	100%	Provider information returns	Annual
Audit Requirements	% of patients who have a copy of the hospital's shared care guideline (SCG) document or have formal shared care arrangements documented between themselves and the secondary care consultant in the patient's notes.	80%	Provider information returns	Annual

3. Scope

3.2 Aims and objectives of service

The treatment of several diseases within the fields of medicine, particularly in rheumatology, is increasingly reliant on drugs that, while clinically effective, need regular blood monitoring. This is due to the potentially serious side effects that these drugs can occasionally cause. It has been shown that the incidence of side effects can be reduced significantly if this monitoring is carried out in a well-organized way, close to the patient's home. Methotrexate is used in the treatment of adults with severe, active, classical or definite rheumatoid arthritis (RA) who are unresponsive or intolerant to conventional therapy. Methotrexate has also been used in the treatment of severe, uncontrolled psoriasis, which is not responsive to other therapy. Methotrexate has been used to produce regression in a wide range of neoplastic conditions. This service applies to all primary care prescribing of methotrexate, including prescribing initiated within the private sector.

The two most common errors that occur that result in harm:-

1. The strength of the tablets is changed and patient ends up taking an incorrect dose
2. Methotrexate is taken daily instead of weekly

3.2 Service description/care pathway

- A shared care drug monitoring and prescribing service in respect of oral methotrexate (excluding prescribing for neoplastic conditions which should at present remain with secondary care). Patients will have been initiated and stabilised on methotrexate in secondary care first, for at least two to three month duration. To qualify for this service the practice must undertake some of the blood monitoring required as detailed in the shared care guidelines.

- The practice will ensure that they are in receipt of a shared care guideline (SCG) document or have formal shared care arrangements documented between themselves and the secondary care consultant (e.g. standard letter sent by secondary care for the GP to formally accept or decline the taking on of the shared care management). SCG documents are available for moderate / severe rheumatoid arthritis and severe psoriasis for patients at Royal Free London Foundation Trust and UCLH (see section 4.3).

- Shared care arrangements and relevant documents should be scanned in or entered into the notes. The acute trust must provide the GP in plenty of time a letter detailing the recommended monitoring arrangements for the individual patient (including exactly which tests are required; frequency of monitoring; folic acid dose and recommended OP attendance intervals). If the consultant does not inform the GP re recommended monitoring interval the GP will assume that it is **two monthly**, as recommended by Barnet CCG.

- Practice will read code indication for methotrexate and maintain a register. (Register should include: all patients on methotrexate indicating - patient name, date of birth and the indication and duration of treatment and last hospital appointment).

- Practices should have clear systems in place for patients who they are prescribing AND undertaking monitoring for (level of the LES service).
  There should be separate systems in place for patients for whom the practice is only prescribing (secondary care undertaking monitoring) or where the hospital prescribes and monitors. This is to ensure that the National Patient Safety Agency recommendations (NPSA) are met.

- Ensure systematic call and recall of patients on the methotrexate register. Practices must ensure the implementation of a robust system to target patients that do not attend for blood test monitoring and hence may not be able to be safely prescribed methotrexate.

- Practice will prescribe oral methotrexate in accordance with the SCG / shared care arrangements and ensure patient understanding. NB Prescription for methotrexate should state the appropriate dose in milligrams, number of tablets and frequency (prescription should NOT say "when required" or "as directed") NB There is a local agreement that only 2.5mg tablets are to be prescribed. To minimise dosing errors 10mg tablets should NOT be prescribed.

- Repeat prescriptions should be retained separately for prescriber review prior to authorising and all methotrexate prescription should be computer generated. Prescriptions should be for a maximum of 2 months duration and the date the patient needs to takes the methotrexate and the folic acid (different day) should be on the prescription.

- Practice will ensure compatibility of methotrexate with other medication taken by the patient and seek advice from consultant if concerned.

- Practice will undertake monitoring as per the SCG / shared care arrangements. N.B. Prescribing should only occur in the presence of timely toxicity monitoring results. If these are not available, the clinician must actively obtain them. GPs must not prescribe methotrexate if no recent test results are available. Blood forms must have the NHS number on them to make it easier for the hospital doctors to access.

- The practice or the patient (e.g. rung up by the practice) will record the blood results, test dates and the weekly dose of methotrexate in the patient's Methotrexate monitoring booklet provided to the patient by secondary care. Normally the acute trust (NHS or private) should provide the patient information booklets to the patients. If the patient does not have a booklet, the practice may decide to purchase copies of the nationally approved one.

- If the practice already sends samples for testing to the patient's secondary care provider then samples should continue to be sent to these laboratories.

- The practice will ensure a robust process for the repeat prescribing of Methotrexate in accordance with NPSA recommendations.

- The practice must reinforce education and advice on the risks and benefits of methotrexate, including management of and prevention of secondary complications of their condition. Patients should be given a copy of the NPSA patient information leaflet if not already supplied by secondary care. Confirmation of the patient's understanding of the risks and benefits of methotrexate should be regularly (not just on a one off situation).

- The practice will refer the patient back to secondary care, other support agencies or discuss any issues with the consultant as per the SCG / shared care arrangement. The hospital must inform the GP ASAP if the patient does not attend OP appointments and /or blood test appointments within the secondary care setting.

- The practice will maintain adequate records of the service provided, incorporating all known information relating to any significant events e.g. hospital admissions, death, of which the practice has been notified.

- The practice will undertake an annual audit as noted in section 2.2

- Practice must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so.

- Practice has updated prescribing software to the required specification stated in the NPSA alert (13).

Pregnancy and Breastfeeding:
Methotrexate is an abortificient as well as a teratogenic drug. Women who are pregnant, attempting to become pregnant or breastfeeding should not use methotrexate. Male partners taking methotrexate must be counseled that the drug may affect sperm and that their partners should avoid pregnancy whilst the drug is being taken.
Patients' should be advised to continue contraception for at least 3 months after stopping methotrexate. Breastfeeding should not be allowed as the drug may be excreted in the breast milk.

Folic Acid:
This is prescribed to reduce side-effects e.g. gastro-intestinal. The dose is 5mg once weekly or more often and this must be explicitly recommended in the patient's letter sent to the GP from the hospital clinician. Folic acid must not be taken on the same the same day as methotrexate.

Pricing:
Each practice contracted to provide this service will receive:

£50 per patient per annum payment will be made based on the number of patients monitored on a shared care basis under this Service.

3.3 Population covered

The practice adult population with rheumatoid arthritis, uncontrolled psoriasis and wide range of neoplastic conditions.

3.4 Any acceptance and exclusion criteria and thresholds

Thresholds:
GPs should prescribe methotrexate at the dose recommended and ensure patient understands the number of tablets and strength of tablets to take. **Only 2.5 mg tablets should be prescribed.** 10 mg tablets **SHOULD NOT** be prescribed. Prescriptions should specify "once a week" and the day of administration. The term "as directed" and 'prn' SHOULD **NOT** be used.

Folic acid supplements:

Folic acid is normally taken to reduce the risk of gastro-intestinal and haematological toxicity. Dosage is within the range of **5 - 10mg once weekly** up to **5 - 10mg once daily** depending on independent consultant preference.

Inclusion Criteria:
Methotrexate is used in the treatment of adults with severe, active, classical or definite rheumatoid arthritis (RA) who are unresponsive or intolerant to conventional therapy.

Methotrexate to be prescribed in the treatment of severe, uncontrolled psoriasis, which is not responsive to other therapy.

Methotrexate has been used to produce regression in a wide range of neoplastic conditions.

Exclusion Criteria:

Methotrexate is an abortificient as well as a teratogenic drug. Women who are pregnant, attempting to become pregnant or breastfeeding should not use methotrexate. Male partners taking methotrexate must be counseled that the drug may affect sperm and that their partners should avoid pregnancy whilst the drug is being taken.
Patients' should be advised to continue contraception for at least 3 months after stopping methotrexate. Breastfeeding should not be allowed as the drug may be excreted in the breast milk.

3.5 Interdependence with other services/providers

N/A

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

Untoward events:
It is a condition of participation in this LES that practitioners will give notification, in addition to their statutory obligations, within 72 hours of the information becoming known to him/her, to Barnet CCG of all serious untoward incidents (e.g. Emergency admissions or deaths) where it was considered that methotrexate directly attributed to this outcome.

All adverse incidents and near misses must be dealt with according to the primary care provider's procedures and guidelines as set out by the Care Quality Commission (CQC). In addition, primary care providers are required to report all incidents to the CCG.

Serious incidents definition.
An incident or near miss occurring on health service premises or in relation to health services provided, resulting in death, serious injury or harm to patients, staff or the public, significant loss or damage to property or the environment, or otherwise likely to be significant public concern. This shall include 'near misses' or low impact incidents which have the potential to contribute to serious harm. The definition also applies to any incident involving the actual or potential loss of personal information that could lead to identify fraud or have significant impact on individuals should be considered as a serious. Please refer to the **Barnet CCG Incidents and Serious Incidents (SIs) Reporting, Investigating and Management Policy imbedded below with the incident form.**

BCCG_SI_Policy_v2.2.pdf Incident_Form.docx

For suspected adverse effects, a yellow card should be submitted.

Accreditation:
Those doctors who have previously provided services similar to the proposed enhanced service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the enhanced service shall be deemed professionally qualified to do so.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

The NPSA website below contains details of the following:

- NPSA Patient Safety Alert 13 - Improving compliance with oral methotrexate guidelines

http://www.nrls.npsa.nhs.uk/resources/?entryid45=59800&q=0%c2%acmethotrexate%c2%ac

- Oral methotrexate pre-treatment patient information leaflet and Patient-held blood monitoring ***and*** dosage record booklet

http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/alerts/oral-methotrexate

4.3 Applicable local standards

North Central London Methotrexate Shared Care Guideline
http://ncl-jfc.org.uk/gp-shared-care-guidelines.html

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4 Parts [A-D])

N/A

5.2 Applicable CQUIN goals (See Schedule 4 Part [E])

N/A

6. Location of Provider Premises

The Provider's Premises are located at:

7. Individual Service User Placement