SHARED CARE FRAMEWORK
FIRST APC BOARD DATE: 27 SEP 2017
LAST APC BOARD DATE: 28 NOV 2018

PENICILLAMINE for patients within adult services

No longer in BSR guidelines this is a framework for existing patients only

1. Background	Penicillamine is a thiol-group containing chelating agent, variably absorbed from the gastrointestinal tract. Penicillamine is strongly plasma-protein bound. About 80% of the absorbed dose is excreted rapidly in the urine, mostly as mixed disulphides. N.B. Penicillamine is not included in the 2017 version of the British Society for Rheumatology guidelines.
2. Licensed Indications	Rheumatoid arthritis Wilson's disease (hepatolenticular degeneration) Chronic active hepatitis in adults
3. Locally agreed off-label use	N/A
4. Initiation and ongoing dose regime	**Rheumatology patients managed by Wirral Trust** Secondary care to diagnose and provide written instructions to the GP for prescribing and escalation of treatment. **Other Patients** Transfer of monitoring and prescribing to Primary care is normally after 3 months **The duration of treatment will be determined by the specialist based on clinical response and tolerability.**
	125mg to 250mg daily for the first month. Increase by the same amount every four to 12 weeks until remission occurs. The usual maintenance dose is 500 to 750mg daily. Up to 1500mg daily may be required. (Daily dosage should not exceed 1000mg in elderly)
	All dose adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician
	Termination of treatment will be the responsibility of the specialist.

<table>
<tr><td>Rheumatology patients managed by Wirral Trust
Baseline investigations to be undertaken by specialist. Initial monitoring and dose titration to be undertaken by GP

Other Patients
5. Baseline investigations, initial monitoring and dose titration to be undertaken by specialist</td><td colspan="2">FBC, Urinalysis (for protein and blood), CRP, ESR, U&E’s: fortnightly for 6 weeks, or longer until dose is stable</td></tr>
<tr><td rowspan="2">6. Ongoing monitoring requirements to be undertaken by primary care.</td><td>Monitoring</td><td>Frequency</td></tr>
<tr><td>FBC, U&E’s, CRP, ESR, Urinalysis (for protein and blood)

CRP and ESR (rheumatology patients only)</td><td>Monthly</td></tr>
<tr><td rowspan="4">7. Pharmaceutical aspects</td><td>Route of administration</td><td>Oral</td></tr>
<tr><td>Formulation</td><td>125mg and 250mg tablets</td></tr>
<tr><td>Administration details</td><td>Penicillamine should be taken on an empty stomach at least half an hour before meals, or on retiring.</td></tr>
<tr><td>Other important information</td><td>Pyridoxine 25 mg daily may be given to patients taking penicillamine for long periods, especially if they are on a restricted diet, since penicillamine increases the requirement for this vitamin</td></tr>
<tr><td>8. Contraindications

Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.</td><td colspan="2">• Hypersensitivity to penicillamine or any of the ingredients.
• Patients with moderate or severe renal insufficiency,
• Lupus erythematosus,
• A history of penicillamine induced agranulocytosis, aplastic anaemia or severe thrombocytopenia.</td></tr>
<tr><td>9. Significant drug interactions</td><td colspan="2">For a comprehensive list consult the BNF or Summary of Product Characteristics. SPC

Seek advice from the initiating Specialist if there are any concerns about interactions.</td></tr>
<tr><td rowspan="5">10. Adverse Effects and managements</td><td>Result</td><td>Action</td></tr>
<tr><td>Abnormal bruising or severe sore throat</td><td>Stop drug until FBC results available, contact Specialist Nurse (SN)</td></tr>
<tr><td>Fall in WCC <3.5 x 10^9/l
Fall in neutrophils <1.6 x 10^9/l
Fall in platelets <140 x 10^9/l</td><td>Stop drug. Contact SN for advice and management</td></tr>
<tr><td>Increased MCV >105f/l</td><td>Check folate, B12 & TSH. Treat if abnormal but contact SN for advice if normal.</td></tr>
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	Unexplained reduction in albumin <30g/l		Stop drug. Contact SN
	Abnormal LFTs – AST or ALT > 100 U/l		Stop drug. Contact SN
	Rash		Discuss with SN.
	Taste loss:		Reassure, continue drug.
	Nausea, vomiting, diarrhoea		Discuss with SN
	Increase in serum creatinine > 30% over period of 12 months or less OR decline in eGFR > 25%		Contact SN if there is new or unexplained renal impairment
	Proteinuria:	Trace	Continue drug
		+	Send MSU to exclude infection
		++ / +++	Send MSU. If negative - stop drug and contact SN
	Haematuria:	Trace	Continue drug
		+	Send MSU to exclude infection
		++ / +++	Stop drug. Send MSU and contact SN
11. Advice to patients and carers	The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual drugs.		
12. Pregnancy and breast feeding	The safety of penicillamine in pregnancy has not been established. Penicillamine should be used in pregnancy and breastfeeding only when the expected benefits outweigh the risks of discontinuing the medication.		
13. Specialist contact information	See specialist communication.		
14. Additional information	**Where patient care is transferred from specialist service or GP practice to another, a new shared care agreement must be completed.**		
15. References	BSR monitoring guidelines		
16. To be read in conjunction with the following documents.	1. Policy for Shared Care 2. Shared care agreement. When two or more DMDs are initiated, one shared care agreement form should be completed for all relevant drugs.		

Appendix 1

Policy for Shared Care

Shared care is only appropriate if it provides an optimum solution for the patient and it meets the criteria outlined in the Shared Care section of the Pan Mersey **Definitions and Criteria for Categorisation of Medicines in the Pan Mersey Formulary** document.

Before prescribing responsibilities are transferred to primary care:

- Prescribing responsibility will only be transferred when the consultant and the patient's GP agree that the patient's condition is stable.
- All information required by the shared care framework for the individual medicine has been provided to the patient's GP.
- Patients will only be referred to the GP once the GP has agreed to the Shared Care Agreement and returned signed copies.

Inherent in any shared care agreement is the understanding that participation is at the discretion of the GP, subject to the availability of sufficient information to support clinical confidence.

Specialist Responsibilities in Shared Care

- For Rheumatology patients under Wirral Trust, Specialist to ensure baseline monitoring of full blood count and biochemical profile as described by the shared care framework
- For all other patients, Specialists to initiate the medicine, prescribe, monitor for toxicity and efficacy as described by the shared care framework until the patient is stabilised.
- To ensure the patient or their carer:
    - Is counselled with regard to the risks and benefits of the medicine.
    - Provide any necessary written information to the patient with regard to the individual medicine including patient information leaflets on individual drugs.
    - Obtain and document informed consent from the patient when any medicines is prescribed for an off-label indication for any condition
- To be familiar with the shared care framework.
- To provide all information to the patient's GP as required by the shared care framework when prescribing responsibility is initially transferred and at any subsequent times as necessary for safe and effective treatment of the patient.

- To assess the patient regularly as necessary for the duration of therapy.
- To review the patient promptly if required by the GP concerned.
- To meet any additional requirements as required by the individual medicine shared care framework.
- To communicate failure of a patient to attend a routine hospital review and advise the GP of appropriate action to be taken.
- **Addition of a second DMD**: Following the addition of a new drug to an existing regime covered by a Shared Care Agreement, the Specialist must initiate, prescribe and monitor the new drug in accordance with the relevant shared care agreement including subsequent review and inform the GP of this. A new Shared Care Agreement must then be initiated for the new drug.

Primary Care Responsibilities in Shared Care

- To reply to a written request for Shared Care within 21 days ensuring both copies of the Shared Care Agreement are signed if appropriate.

If agreeing to shared care, the GP is asked to:

- To provide prescribe or manage and monitor the medicine as advised by the Specialist and in line with the individual Shared Care Framework.
- To review the patient as required by the Shared Care Framework
- To make appropriate and contemporaneous records of prescribing and/or monitoring and to note the existence of the Shared Care Agreement on the patient`s clinical record. A READ code of “6652 Shared Care- Specialist/GP” can be used.
- To be familiar with the individual Shared Care Framework.
- To report any adverse effects of treatment to the specialist team.
- To inform the Specialist of any relevant change in the patient’s circumstances.
- To seek Specialist advice as appropriate.
- To meet any additional requirements as required by the individual Shared Care Framework.
- To respond to Specialist communication relating to any change or addition to the patients treatment covered by the Shared Care Agreement.

Appendix 2: Shared Care Agreement

Disease modifying drugs (DMDs)

Request by Specialist Clinician for the patient's GP to enter into a shared care agreement

Part 1
To be signed by Consultant / Prescribing member of Specialist Team

Date _____

Name of patient _____

Address _____

_____

Patient NHS No _____

Patient hospital unit No _____

Diagnosed condition _____

If using addressograph label please attach one to each copy

Dear Dr _____

I request that you prescribe

(1) _____

(2) _____

(3) _____

(4) _____

for the above patient in accordance with the enclosed shared care framework.

Last Prescription Issued: ….. / ….. / ….. Next Supply Due: ….. / ….. / …..

Date of last blood test: ….. / ….. / ….. Date of next blood test: ….. / ….. / …..

Frequency of blood test: ……

I confirm that the patient has been stabilised and reviewed on the above regime in accordance with the Shared Care Framework and Policy. ☐

I confirm that if this is a Shared Care Agreement for a drug indication which is unlicensed or off label, informed consent has been received. ☐ N/A

Details of Specialist Clinicians

Name_____Date_____

Consultant / Prescribing member of the Specialist Team ***circle or underline as appropriate***

Signature _____

In all cases, please also provide the name and contact details of the Consultant.

When the request for shared care is made by a prescriber who is not the consultant, it is the supervising consultant who takes medico-legal responsibility for the agreement.

Consultant: _____

Contact details*:*

Telephone number: _____Ext:_____

Address for return of documentation _____

_____

_____

Part 2
To be completed by Primary Care Clinician

Patient name _____

I agree to prescribe_____for the above patient in accordance with the enclosed shared care framework.

GP signature_____Date _____

GP name _____Please print

GP: *Please sign and return a copy* ***within 21 calendar days*** *to the address above*

OR

GP- If you do not agree to prescribe, please delete the section above and provide any supporting information as appropriate below: