Midlands and Lancashire
Commissioning Support Unit

Shared care protocol

Dapsone for the treatment of Dermatitis Herpetiformis, other dermatoses and Vasculitis.

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Local review and adoption

Local approval	Date
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Shared Care Protocol

Dapsone for the treatment of Dermatitis Herpetiformis, other dermatoses and Vasculitis

1. Background	Dapsone is an antibacterial medicine belonging to the sulphonamide class of antibiotics, which inhibits the synthesis of folic acid. It acts as an anti-inflammatory drug and has been used successfully as a treatment for several skin conditions such as dermatitis herpetiformis, pyoderma gangrenosum, Sweet's syndrome and vasculitis for many years. It can also be used for other inflammatory skin conditions. The early side effects are haematological and are dose related. Peripheral neuropathy although an uncommon side effect is clinically significant due to its frequent subtle onset and the high potential for long term persistence even after the cessation of therapy.

2. Licensed and agreed off-label indications	Licensed indications relevant to this document: Treatment of dermatitis herpetiformis and other dermatoses.[1] Unlicensed relevant to this document: Vasculitis Dapsone is also licensed for several other indications which are beyond the scope of this document.
3. Locally agreed indications	In addition to the above licensed indications, LSCMMG have agreed to the following use(s) for shared care: Dermatitis Herpetiformis and other dermatoses. Vasculitis.
4. Initiation and ongoing dose regime	Transfer of monitoring and prescribing to primary care should be after at least 3 months, and when the patient's dose has been optimised and with satisfactory investigation results for at least 1 month. The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability. All dose or formulation adjustments and consequent monitoring will be the responsibility of the specialist unless directions have been discussed and agreed with the primary care clinician. Termination of treatment will be the responsibility of the specialist. For dermatitis herpetiformis commence 50mg daily and increase gradually up to 300mg daily if required. Once lesions have begun to subside, the dose should be reduced to a minimum as soon as possible, usually 25 to 50mg daily, which may be continued for a number of years. Maintenance dose can often be reduced in patients on a gluten-free diet. Elderly: Dosage should be reduced in the elderly where there is an impairment of hepatic function. Dapsone is available as 50mg and 100mg tablets

5. Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist	Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in the immediate future will prescribing and monitoring be transferred to primary care. **<u>Baseline investigations:</u>** **Baseline** FBC, U&Es, LFTs, Reticulocyte count, G6PD enzyme levels. Perform baseline neurological assessment in order to detect subsequent development of peripheral neuropathy. This should include: 10g filament test of sensory function,128 Hz tuning fork to test vibration, testing ankle jerk and muscle strength of lower limbs. **Initiation** FBC every 2 weeks for 8 weeks, then every 3 months thereafter, unless advised otherwise by Secondary Care LFTs every month until stable and then 3 monthly once stable

6. Ongoing monitoring requirements to be undertaken by primary care If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.	**<u>Monitoring</u>**	**<u>Frequency</u>**
	FBC, U&E, LFT, Reticulocyte count	Every 3 months, seek advice from initiating specialist should results be deranged.
	STOP Dapsone and seek advice if: WBC < 3.5 x 10^9/L Neutrophils < 2.0 x 10^9/L Platelets < 150 x 10^9/L AST/ALT > 2 times the upper limit of reference range **CAUTION if:** MCV > 105fL Check thyroid function, B12 and folate and supplement if necessary. Hb falls > 20gm/L from baseline – STOP and seek advice Hb fall > 1gm in 4 weeks – check for increased disease activity. Ask about NSAID use and symptoms of GI blood loss or dyspepsia and stop NSAIDs if implicated. Check MCV and iron studies. Consider endoscopy. N.B: the use of glycosylated haemoglobin (HbA1c) to monitor diabetes mellitus can be unreliable on dapsone due to the risk of haemolysis and the formation of methaemoglobin which interferes with the measurement HbA1c	

7. Pharmaceutical aspects

Route of administration:	Oral
Formulation:	Tablets: 50mg and 100mg
Administration details:	Once daily

Other important information:	Dapsone contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
8. Cautions and contraindications	This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF and SPC for comprehensive information. **Contraindications:** • Hypersensitivity to dapsone (other sulphonamides / sulphones)or any of the excipients • Severe anaemia • Porphyria • Severe glucose-6-phosphate dehydrogenase deficiency. **Cautions:** • Dapsone should be used with caution in patients with cardiac or pulmonary disease. It is recommended that regular blood counts be performed during treatment with dapsone. • Patients deficient in glucose-6-phosphate dehydrogenase, or methaemoglobin reductase, or with haemoglobin M are more susceptible to the haemolytic effects of dapsone. • Dapsone should be used with caution in anaemia. Severe anaemia should be treated before starting Dapsone
9. Significant drug interactions	The following list is not exhaustive. Please see BNF and SPC for comprehensive information and recommended management. • Probenecid: Excretion of dapsone is reduced and plasma concentrations are increased by concurrent administration of probenecid. • Rifampicin/ Rifabutin: has been reported to increase the plasma clearance of dapsone. • Saquinavir: should not be used in combination, as this could increase the risk of irregular heartbeat. • Trimethoprim: Increased dapsone and trimethoprim concentrations have been reported following concurrent administration in AIDs patients. • Oral typhoid vaccine: should not be taken until at least three days after finishing a course of dapsone, because the dapsone could make this vaccine less effective
10. Adverse effects and management	As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance. For information on incidence of ADRs see relevant SPCs.

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard.

The undesirable effects are listed below by organ class and the following frequency convention:

Very common	≥ 1/10 users	**Rare**	≥ 1/10,000users; <1/1000 users
Common	≥ 1/100users; <1/10 users	**Very rare**	<1/10,000 users
Uncommon	≥ 1/1000users; <1/100 users	**Unknown**	Cannot be estimated

System Organ Class(SOC)	**Frequency**	**Undesirable effect**
Blood Disorders:	Common	Haemolysis
		Methaemoglobinaemia
	Uncommon	Haemolytic anaemia
	Rare	Agranulocytosis
Cardiac Disorders:	Uncommon	Tachycardia
Gastrointestinal Disorders:	Uncommon	Anorexia
		Nausea
		Vomiting
General Disorders:	Rare	**Dapsone Syndrome***
Hepatic Disorders:	Uncommon	Hepatitis
		Jaundice
		Changes in liver function tests
Metabolic Disorders:	Uncommon	Hypoalbuminaemia
Nervous System Disorders:	Uncommon	Headache Neuropathy peripheral Peripheral motor neuropathy
Psychiatric Disorders:	Uncommon	Insomnia
		Psychoses
Skin Disorders:	Uncommon	Photosensitivity
		Pruritis
		Rash
	Rare	Exfoliative dermatitis
		Maculopapular rash
		Toxic epidermal necrolysis
		Stevens – Johnson syndrome
	Very rare	Fixed drug eruptions
*** If dapsone syndrome occurs (rash with fever and eosinophilia)—discontinue immediately (may progress to exfoliative dermatitis, hepatitis, hypoalbuminaemia, psychosis and death).**		

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, paternal exposure and breastfeeding	**Pregnancy:** Dapsone should only be given during pregnancy when benefit outweighs risk. If dapsone has to be taken in pregnancy then the mother should take folic acid 5mg daily. **Breast-feeding:** Dapsone diffuses into breast milk and there has been a report of haemolytic anaemia in a breast fed infant. Although significant amount in milk, risk to infant is very small unless infant is G6PD deficient.
13. Specialist contact information and arrangements for referral	The specialist team should: • make contact with the patient's GP requesting them to prescribe under a shared care agreement as soon as practicably possibly after the initial supply has been provided to the patient. Please note secondary care retains responsibility for monitoring and supply until the GP has agreed to prescribe under this shared care agreement. • Share the results of any blood monitoring with primary care. • Reassess the patient after 3 months for clinical response. • Prior to entering into a shared-care agreement, secondary care will advise the GP on frequency of monitoring, management of any dose adjustments and when to stop treatment. • Secondary care should ensure that clear backup arrangements exist for GPs to obtain advice if required.
14. Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

References

[1] EMC https://www.medicines.org.uk/emc/product/11737/smpc