



Surrey Heartlands Integrated Care System Area Prescribing Committee (APC)

Integrated Care Partnerships (ICPs) (Surrey Downs, Guildford & Waverley, North West Surrey, East Surrey (as part of the CRESH system) & associated partner organisations.

INFORMATION SHEET – Blue Traffic Light Classification	
Name of medicine	Sildenafil
Indication (including whether for adults and/or children)	Raynaud's Phenomenon secondary to systemic sclerosis (Not for primary Raynaud's Phenomenon)
APC policy statement reference (if applicable)	N/A
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The information sheet is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface for medicines classified by Area Prescribing Committee (APC) as **BLUE**

BLUE drugs are considered suitable for prescribing in primary care, following initiation and stabilisation by a specialist as ongoing monitoring can be undertaken in primary care without specialist support and WITHOUT the need for a formal shared care guideline.

For each drug classified as **BLUE**, the Area Prescribing Committee will recommend the minimum supply and whether an information sheet is required or not. A minimum of one month's supply of medication will be provided by the initiating consultant.

This information sheet sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications. A GP or Primary Care Prescriber must ensure they are familiar with the prescribing responsibilities. This information sheet is available on the internet <http://pad.res360.net/> forming part of the Prescribing Advisory Database (PAD) giving GPs appropriate advice / guidance and is not required to be sent to the GP with the clinic letter.

RESPONSIBILITIES and ROLES

Consultant / Specialist responsibilities	
1.	Diagnosis
2.	To assess the suitability of patient for sildenafil treatment for the Off-label" use for Raynaud's phenomena associated with systemic sclerosis. Treatment must be initiated and monitored by a specialist experienced in the diagnosis and treatment of Raynaud's disease in accordance with national and international best practice, when the following criteria apply: <ul style="list-style-type: none"> • Patient has severe Raynaud's secondary to systemic sclerosis. • Patient is following lifestyle management (proper body insulation, avoidance of cold exposure, smoking cessation support, avoidance of sympathomimetic drugs) • Patient has persisting severe symptoms despite standard treatment with calcium channel blockers and angiotensin receptor blockers (unless contraindicated or not tolerated). • Treatment will usually be offered prior to the use of iloprost.
3.	To discuss the aims, benefits and side effects of treatment with the patient and/or carer as well as their role
4.	Explain to the patient and/or carer the treatment plan including the dosing schedule <ul style="list-style-type: none"> • Treatment is usually initiated at 25mg three times a day as per national guidance. • The specialist will prescribe the first month of sildenafil treatment and ensure the patient understands their treatment, including which side effects to report promptly and advise the patient to stop treatment if they experience hypotensive side effects. • The dose may be further increased (by the specialist) to 50mg three times a day in accordance with response and tolerability. • There is no evidence to suggest that dose reduction is required for patients >65yrs.
5.	Perform any baseline monitoring required prior to treatment. To include blood pressure and rule out significant ischaemic heart disease (IHD)
6.	Monitor and evaluate response to treatment, including adverse drug reactions, with the patient and to continue / discontinue treatment in line with agreed treatment plan
7.	Supply GP with summary of patient review (including anticipated length of treatment) and a copy of the information sheet.

8. Advise GP if treatment is to be discontinued at any point

9. Inform GP if patient does not attend planned follow-up

General Practitioner (GP) or Primary Care Prescriber responsibilities

1. Subsequent prescribing of generic sildenafil at the dose recommended by the specialist.

2. Check for any interactions before prescribing other medicines with sildenafil

3. Monitor patient's blood pressure after 1st prescription (usually 1 month) and then again (including postural hypotension) if the patient is symptomatic or every 6 months.

4. Identify and report any adverse events to the specialist and MHRA and take appropriate action

Patient / Carer role

1. Informing the specialist team, primary care prescriber or other healthcare professional if he or she has further questions or wants more information about the treatment

2. Tell the consultant / specialist or GP or Primary Care Prescriber of any other medication being taken, including over-the-counter products.

3. Sharing any concerns about their treatment and problems they are having taking their medicines with the specialist team, primary care prescriber or other healthcare professional involved in their care

4. Supported to know how to report any adverse effects to the specialist team, primary care prescriber or other healthcare professional involved in their care, and how adverse effects can be managed

5. To be available for monitoring as required

6. Attend follow-up appointments with the consultant / specialist / GP. **Non-attendance of appointments without good reason, may result in treatment being stopped**

7. Read the patient information leaflet included with your medication and report any side effects or concerns you have to the consultant / specialist or Primary Care Prescriber.

8. In the event of any sudden visual defect patients should stop taking sildenafil and consult a doctor immediately.

Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC) for sildenafil, available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication

Raynaud's Phenomenon (RP) can be primary (80-90%) or secondary (10-20%). RP involves the vasospasm of blood vessels in the extremities such as the digits. This can cause the affected area to change colour and can be painful, limiting everyday tasks.

Primary RP does not have a link to any other disease and secondary RP can be a sign of a potentially serious health condition, usually an auto-immune condition e.g. lupus, vasculitis and scleroderma/systemic sclerosis.

In severe RP digital ulcers can occur and are associated with digital vasculopathy. They can be painful and difficult to treat and heavily impair a person's quality of life.

The aim of treatment is to improve symptoms such as pain and loss of hand function but also to heal any ulcers present, prevent new ulcers from forming, prevent infection and reduce any associated morbidity.

Dosage and Administration

Treatment with sildenafil is usually initiated at 25mg three times a day as per national guidance. The dose may be further increased (by the specialist) to 50mg three times a day in accordance with response and tolerability. No dose reduction is required for patients >65yrs.

Expected outcome

Use of sildenafil may avoid or delay the need for a patient to have iloprost infusion.

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC) for sildenafil: www.medicines.org.uk

Adverse effects - Refer to current Summary of Product Characteristics (SPC) for sildenafil: www.medicines.org.uk

Drug interactions - Refer to current Summary of Product Characteristics (SPC) for sildenafil: www.medicines.org.uk