

## DORSET MEDICINES ADVISORY GROUP

### COMMISSIONING STATEMENT ON MIRVASO® 3mg/g GEL (BRIMONIDINE TARTRATE) FOR FACIAL ERYTHEMA OF ROSACEA IN ADULTS.

<b>SUMMARY</b> NHS Dorset Clinical Commissioning Group recommends the use of Mirvaso® 3 mg/g gel (brimonidine tartrate) for the symptomatic treatment of facial erythema of rosacea in adult patients.	
<b>BACKGROUND</b>	<p>Mirvaso® 3 mg/g gel contains brimonidine tartrate 3.3 mg /g, equivalent to 5 mg/g and is indicated for the symptomatic treatment of facial erythema of rosacea in adult patients. Brimonidine tartrate is a highly selective alpha -2 adrenergic receptor agonist, with potent vasoconstrictive and vasostabilising activity. It is an aqueous gel applied to the face once daily.</p> <p>Rosacea is a chronic relapsing disease of facial skin, characterised by recurrent episodes of facial flushing, persistent erythema, telangiectasia, papules and pustules. For the symptoms of flushing and erythema there is historically no effective treatment and management generally consists of lifestyle advice, including applying sunscreen and avoiding trigger factors when practical.</p>
<b>RELEVANT NICE GUIDANCE</b>	<p>NICE produced advice as Evidence Summary: New Medicine (ESMN43) Facial erythema of rosacea: brimonidine tartrate gel in July 2014.</p> <p>Mirvaso® gel is not considered for a NICE technology appraisal and is not currently planned into any other NICE work programme.</p>
<b>FORMULARY STATUS</b>	<p>Amber with shared care guidance. May be initiated by a GPSI or community based service, or by the patient's GP following receipt of advice and guidance from secondary care dermatology services</p>
<b>PbR STATUS</b>	<p>Included in tariff</p>
<b>COMMISSIONING IMPLICATIONS</b>	<p>Patients with flushing, erythema (without inflammation), telangiectasia, should be provided with lifestyle advice (for mild rosacea), which should include a review of drug therapy (some drugs can aggravate flushing e.g. calcium-channel blockers, so should be avoided where possible) or referral to secondary care.</p> <p>Flushing may be helped by propranolol 40 mg bd, or clonidine 50 mcg bd. Neither is licensed for rosacea or included in the dermatology formulary.</p> <p>Brimonidine topical gel is an option which might benefit some, but not all, patients with persistent erythema. Brimonidine tartrate gel is a third line agent for facial erythema of rosacea in adult patients provided that patients have tried all other alternatives and that redness is a significant problem".</p> <p>The Medicines and Healthcare Products Regulatory Agency (MHRA) issued an alert in 2017 of a risk of systemic cardiovascular effects following application of brimonidine gel to damaged skin.</p>

	<p><a href="https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-systemic-cardiovascular-effects-not-to-be-applied-to-damaged-skin">https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-systemic-cardiovascular-effects-not-to-be-applied-to-damaged-skin</a>.</p> <p>The MHRA issued a previous alert for brimonidine gel in 2016 of a risk of exacerbation of rosacea in up to 16% of patients treated with the gel. They noted “It is important to initiate treatment with a small amount of gel and increase the dose gradually, based on tolerability and treatment response”. <a href="https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-exacerbation-of-rosacea">https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-exacerbation-of-rosacea</a>.</p> <p>An All Wales Medicines Strategy Group (AWMSG) Clinical expert summary 27/08/15 stated, “It was highlighted by experts that the effect of topical brimonidine on erythema is short lasting. They felt that it should not be used daily since it has an extreme pallor effect and an extreme rebound reaction after 12 hours; generally patients would be advised to limit its use to special occasions where pallor is required temporarily. One exception however, might be when the patient’s occupation involves facing the public on a daily basis; then a regular treatment may be necessary.”</p> <p>Although camouflage e.g. green cream, is recommended, this is not commissioned in Dorset. The charity ‘<a href="#">Changing Faces</a>’ runs clinics in Pelhams Community Health Clinic, Millhams Road, Bournemouth.</p>									
<p><b>RELEVANT CLINICAL WORKING GROUP/RIGHT CARE WORKSTREAM</b></p>	<p>Dermatology</p>									
<p><b>PATIENT PATHWAY IMPLICATIONS</b></p>	<p>The Primary Care Dermatology Society provides comprehensive guidance on rosacea at <a href="http://www.pcds.org.uk/clinical-guidance/rosacea">http://www.pcds.org.uk/clinical-guidance/rosacea</a>. NICE CKS is available at <a href="https://cks.nice.org.uk/rosacea-acne#!scenario">https://cks.nice.org.uk/rosacea-acne#!scenario</a></p>									
<p><b>SUMMARY OF EVIDENCE TO SUPPORT FORMULARY STATUS</b></p>	<p>See summary of product characteristics and NICE Evidence summary: <a href="https://www.medicines.org.uk/emc/product/5303/smpc">https://www.medicines.org.uk/emc/product/5303/smpc</a></p> <p><a href="https://www.nice.org.uk/advice/esnm43/chapter/Key-points-from-the-evidence">https://www.nice.org.uk/advice/esnm43/chapter/Key-points-from-the-evidence</a></p>									
<p><b>ASSESSMENT OF COST IMPLICATIONS</b></p>	<p>Selected comparator treatment costs are summarised below (Drug Tariff Sept 18):</p> <table border="1" data-bbox="523 1765 1508 1928"> <thead> <tr> <th>Drug</th> <th>Usual dose</th> <th>Approx. cost/month</th> </tr> </thead> <tbody> <tr> <td>Propranolol 40mg tabs</td> <td>40mg bd</td> <td>£2.04</td> </tr> <tr> <td>Brimonidine 0.33% gel (Mirvaso®) 30g tube</td> <td>Max 1g od</td> <td>£33.69</td> </tr> </tbody> </table>	Drug	Usual dose	Approx. cost/month	Propranolol 40mg tabs	40mg bd	£2.04	Brimonidine 0.33% gel (Mirvaso®) 30g tube	Max 1g od	£33.69
Drug	Usual dose	Approx. cost/month								
Propranolol 40mg tabs	40mg bd	£2.04								
Brimonidine 0.33% gel (Mirvaso®) 30g tube	Max 1g od	£33.69								

REFERENCES	<p>National Institute of Clinical Excellence. Facial erythema of rosacea: brimonidine tartrate gel. Evidence Summary: New Medicine. ESNM43 London: NICE; July 2014  <a href="https://www.nice.org.uk/advice/esnm43/chapter/Key-points-from-the-evidence">https://www.nice.org.uk/advice/esnm43/chapter/Key-points-from-the-evidence</a></p> <p>Scottish Medicines Consortium (SMC). Submission: brimonidine 0.33% gel (Mirvaso). Published on 12<sup>th</sup> January 2015  <a href="https://www.scottishmedicines.org.uk/medicines-advice/brimonidine-mirvaso-fullsubmission-101614/">https://www.scottishmedicines.org.uk/medicines-advice/brimonidine-mirvaso-fullsubmission-101614/</a></p> <p>All Wales Medicine Strategy Group (AWMSG) Final Appraisal Recommendation Advice No: 2168. Brimonidine (Mirvaso®) 3mg/g gel. 23/05/2014.  <a href="http://www.awmsg.org/awmsgonline/app/appraisalinfo/2168">http://www.awmsg.org/awmsgonline/app/appraisalinfo/2168</a></p> <p>Summary of Product Characteristics. Mirvaso 3mg/g Gel. Galderma (UK) Ltd. Accessed in Sept 2018  <a href="https://www.medicines.org.uk/emc/product/5303/smpc">https://www.medicines.org.uk/emc/product/5303/smpc</a></p> <p>Primary Care Dermatology Society – Rosacea. Accessed in Sept 2018 via  <a href="http://www.pcds.org.uk/clinical-guidance/rosacea">http://www.pcds.org.uk/clinical-guidance/rosacea</a></p> <p>NICE CKS Rosacea January 2016. Accessed in Sept 2018 via  <a href="https://cks.nice.org.uk/rosacea-acne#!scenario">https://cks.nice.org.uk/rosacea-acne#!scenario</a></p> <p>British National Formulary. BMJ Group and RPS Publishing. London; Accessed in September 2018 via <a href="https://bnf.nice.org.uk/drug/brimonidine-tartrate.html">https://bnf.nice.org.uk/drug/brimonidine-tartrate.html</a></p> <p>MHRA. Brimonidine gel (Mirvaso): risk of systemic cardiovascular effects; not to be applied to damaged skin. Published June 2017. Accessed in September 2018 via  <a href="https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-systemic-cardiovascular-effects-not-to-be-applied-to-damaged-skin">https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-systemic-cardiovascular-effects-not-to-be-applied-to-damaged-skin</a></p> <p>MHRA. Brimonidine gel (Mirvaso): risk of exacerbation of rosacea. Published November 2016. Accessed in Sept 2018 via  <a href="https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-exacerbation-of-rosacea">https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-exacerbation-of-rosacea</a></p>
Date	Sept 2018
Review date	First published March 2015, reviewed by dermatology working group July 2018. For review July 2020 or before in the light of new evidence.
Contact for this Policy	Michelle Trevett, Senior Pharmacist, NHS Dorset CCG.