NHS
Calderdale
Clinical Commissioning Group

Commissioning Statement

Treatment	**Brimonidine Gel** Mirvaso® (Galderma) 3mg/g gel
For the treatment of	Brimonidine is indicated for the symptomatic treatment of facial erythema of rosacea in adult patients.
Commissioning position	**NHS Calderdale CCG** does **not** routinely commission the use of Brimonidine gel. Brimonidine gel is considered to be cosmetic in nature and therefore not recommended for prescribing.
Date effective from	27th September 2018
Policy to be reviewed by	September 2021 [To be reviewed earlier if NICE issues guidance at an earlier date]
Background information	Brimonidine tartrate gel is a symptomatic treatment with a transient effect on erythema. It can be used up to once per day, on a daily or as-required basis. Brimonidine works by activating the alpha2-adrenergic receptors in the blood vessels, causing vasoconstriction [1].
Summary of evidence/rationale	**<u>Clinical effectiveness</u>** The two pivotal phase 3 studies and a further supportive long term open label trial consistently demonstrated the efficacy of brimonidine gel against placebo in terms of improvement in Clinician Erythema Assessment (CEA) and Patient Self-Assessment (PSA), (which were considered clinically relevant), but only whilst receiving active treatment. It should be noted that the success rate (defined as a 2 grade reduction in the CEA and PSA) were 25% to 30% with brimonidine gel compared to 10% for the vehicle gel (placebo) at day 29 [1]. A review of evidence by Cochrane on treatments for rosacea further supports the efficacy of brimonidine gel [2]. However it should be noted that the studies conducted were in people with moderate to severe erythema; there is no evidence to support its use in people with less severe erythema as per licensed indication [1]. The two pivotal studies were judged to be relatively short, considering the type of condition being managed, with an active treatment period of

4 weeks [1].

Following 4 weeks of non-treatment the CEA returned to close to pre-treatment scores and some subjects showed worsening on PSA and CEA scores relative to baseline [1].

There are no randomised data available assessing the efficacy of brimonidine gel in patients who are also being treated with other topical products used in the management of rosacea e.g. metronidazole, azelaic acid gel. The open-label long-term study did permit other treatments and almost 30% used additional topical products [1].

Safety

Highest response rates were observed 3 and 6 hours after once daily application of brimonidine gel and tended to wear off at later time points. There is some concern that due to the effect wearing off throughout the course of the day there may be a tendency for some patients to use further applications [1].

The most common adverse reactions with brimonidine gel are erythema, pruritus, flushing and skin burning sensation (occurring in between 1.2% and 3.3% of people in clinical studies) [1, 3].

Further MHRA drug safety updates have since been published. The update reports cases of 'bradycardia, hypotension (including orthostatic hypotension), and dizziness after application of brimonidine gel, some of which required hospitalisation' [4].

References:

1. National Institute of Clinical Excellence. Facial erythema of rosacea: brimonidine tartrate gel. Evidence Summary: New Medicine. ESNM43 London: NICE; January 2013. Accessed from: NICE ESNM43 Facial erythema of rosacea: brimonidine tartrate gel on 05.09.2017

2. http://www.cochrane.org/CD003262/SKIN_treatments-rosacea Accessed on: 05.09.2017

3. Medicines and Healthcare products Regulatory Agency; Drug safety update. Brimonidine gel (Mirvaso): risk of exacerbation of rosacea. November 2016. Accessed from: https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-exacerbation-of-rosacea on: 05.09.2017

4. Medicines and Healthcare products Regulatory Agency; Drug safety update. Brimonidine gel (Mirvaso): risk of systemic cardiovascular effects; not to be applied to damaged skin. June 2017. Accessed from: https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-systemic-cardiovascular-effects-not-to-be-applied-to-damaged-skin on:

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