

## DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

### Principles to determine JAPC Traffic Light classification for Medical Devices and Appliances (MDaAs) which may be prescribed on Fp10

#### Background

MDaAs in the UK are regulated by the MHRA. The MHRA assess whether benefits outweigh risk, they do not consider cost or affordability. MDaAs are used throughout the NHS and there are hundreds of medical devices which could and are routinely prescribed. It is not the intent of these principles to traffic light every available medical device, many will be well established and part of routine healthcare practice. There is however an increasing trend to gain MHRA/EU authorisation under Medical Device legislation rather than Medicine legislation for “borderline” products as the requirements are less stringent for the manufacturer.

#### Aim

To provide clarity on the appropriate use of MDaAs to ensure patients receive timely, safe and effective care in the appropriate care setting.

#### Application

These principles broadly apply to the following scenarios where devices could be prescribed on FP10:

- The MDaA is new to market and has been included in the NHS Drug Tariff
- The MDaA is established, but is considered non-routine or specialist or for limited use
- There is a lack of clarity of responsibilities to prescribe/supply across care interfaces including initiation, stabilisation and maintenance
- Local intelligence (e.g. ePACT data search) which may reveal issues such as safety concerns, variance and cost

#### Principles

- Is the MDaA available via FP10? If not it is the responsibility of the requesting/initiating care provider to assess appropriateness, ensure initiation and on-going supply
- Who is requesting the traffic light classification?
- Any request from a NHS provider/trust/specialist must come via the appropriate Trust decision making committee responsible for MDaA (e.g. Drugs and Therapeutics Committee)
- Requests shall only be made to JAPC using agreed templates: JAPC Front Page Template, and for “new” MDaAs JAPC New Drugs Template  
[www.derbyshiremedicinesmanagement.nhs.uk/japc/japc\\_templates](http://www.derbyshiremedicinesmanagement.nhs.uk/japc/japc_templates)
- JAPC will consider MDaAs using best available evidence using Barber’s Box criteria: Safety, Effectiveness, Patient Factors, and Cost.
- JAPC will consider clinician competencies to prescribe as clinical accountability rests with the prescriber
- JAPC will determine appropriate traffic light classification. JAPC members shall be required to communicate and implement recommendations as required to their respective organisations and clinicians. Traffic light status shall be clearly defined in all patient/treatment pathways relevant to the MDaA