Worcestershire Area
Prescribing Committee
June 2016

Position Statement

Medical Devices

Commissioning Position	**Medical devices* not included in the Worcestershire Joint Medicines formulary, which includes the Wound Management formulary and Continence Product formulary, should NOT be routinely prescribed on FP10 prescription.** • Formulary restrictions apply equally to the prescribing of medical devices as they do to drugs. • A range of medical devices are available, some of which are listed in the Drug Tariff and therefore could be prescribed on FP10 prescription. • Medical devices listed in the Drug Tariff are subject to the Worcestershire Area Prescribing Committee (APC) new medicines application process, with decisions on patient pathways and prescribing responsibility agreed locally. • Local patient pathways should ensure that initial prescribing of a formulary medical device is accompanied by appropriate instruction and counselling.
Definition	*A medical device is defined by the Medical Device Directive as: *'Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:* *- Diagnosis, prevention, monitoring, treatment or alleviation of disease or compensation for an injury or handicap.* *- Investigation, replacement or modification of the anatomy or of a physiological process* *- Control of conception.* *and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means…'* Medical Devices in the UK are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) [1] which is an executive agency of the Department of Health.
Reference	1. How the Medicines and Healthcare products Regulatory Agency (MHRA) makes decisions on what is a medicine or medical device (borderline products). June 2013 Medicines and Healthcare products Regulatory Agency (MHRA).https://www.gov.uk/guidance/decide-if-your-product-is-a-medicine-or-a-medical-device
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