5.8.1 Interim Process for Approval and Management of Medicines Access Schemes during the COVID-19 Pandemic



Introduction

This policy outlines the process for the approval of medicine access schemes during the COVID-19 pandemic. It is interim guidance based on the forthcoming Medicines Access Scheme policy

Overview of Process Access schemes for unlicensed medicines or indications Access schemes for licensed medicines or indications Post-licence (Pre-HTA) Free of Charge Access Scheme **EAMS Other Schemes** (Early Access to Medicines (E.g. Expanded or Scheme) compassionate access) Post-licence (Pre-HTA) Free of Charge Access Scheme **Operational Guidance** issued by ADTC Collaborative? National Guidance considers whether true unmet need and financial risks of scheme Consideration by ADTC YES NO and/or PMGAS Has the FOC Scheme been endorsed by National Procurement? EAMS highlighted to EAMS considered service for acceptable for use YES NO implementation. within NHSGGC? Direct to NP for review YES NO No requirement for of scheme or if more ULM Forms if EAMS is urgent, consideration related to COVID-19 by ADTC/PMGAS Routine ULM access Form All other requests for not access via EAMS expecte **IPTR/PACS2** d. require ULM Form to Individu (Depending on current HTA status) be completed al access

Considerations for ADTC and/or PMGAS:

Request will be considered in accordance with the policy for the relevant process

- 1. Is there a need to consider this medicine now or can the medicine wait until it is licensed?
- 2. Are there any viable licensed alternatives?
- 3. What are the arrangements for withdrawal from the scheme (e.g. how will pricing change upon licensing or following assessment by the SMC? The preference is that free of charge supply will remain in place until either the patient completes/discontinues the treatment or until such a time that the SMC have accepted the medicine and indication for use in NHS Scotland
- 4. What are the workload/administrative implications for NHS Staff?

File name: 5.8.1 Interim Process for Medicines Access Schemes (COVID-19) v1.0

Written by: R. Foot

Approved by: Area Drug and Therapeutics Committee Executive

Date of last revision: 12/08/2020

Date Approved: 12/08/2020

Date for Review: 01/08/2021