From the Chief Medical Officer
Professor Sir Michael McBride

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Castle Buildings
Stormont Estate
BELFAST
BT4 3SQ

Tel: 028 9052 0563
Email: Michael.McBride@health-ni.gov.uk

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FOR ACTION

Chief Executives, Public Health Agency/HSC Trusts/NIAS
Deputy Secretary SPPG
GP Medical Advisers, SPPG
All General Practitioners and GP Locums (for onward distribution to practice staff)
OOHs Medical Managers (for onward distribution to staff)

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

TECOVIRIMAT AS A TREATMENT FOR PATIENTS HOSPITALISED DUE TO MONKEYPOX VIRAL INFECTION

HSC Trusts are asked to:

1. Offer tecovirimat to eligible symptomatic hospitalised patients in line with the published UK wide interim clinical policy statement.
2. Note that initial supply of tecovirimat will be available within 'emergency use' packaging, based on United States Food and Drug Administration (FDA) product labelling. The packaging therefore differs from the Great Britain and European regulatory packaging / labelling requirements, effectively meaning that provision of tecovirimat under the interim UK policy statement should be considered as an **unlicensed use of the medicine**. As such, any organisation treating patients with tecovirimat as an unlicensed product will be required to assure itself that the necessary internal governance arrangements have been completed before the medicine is prescribed. These arrangements may be through the Trust drugs and therapeutics committee, or equivalent.
3. Note that supply will be held by Belfast HSC Trust, and will be made available for supply to other Trusts if needed. For hospitalised patients being treated in other Trusts, including paediatric patients, arrangements will need to be made for the transfer of tecovirimat supply in liaison with the pharmacy department at the Royal Victoria Hospital, Belfast HSC Trust.
4. Ensure that treatment decisions for children, and for individuals who are pregnant, are guided by multi-disciplinary team advice, as set out in the interim clinical policy statement.
5. Actively support recruitment of patients with laboratory confirmed monkeypox infection and with active skin or mucosal lesions, but who do not require hospital admission, to the PLATINUM trial.

Tecovirimat, manufactured by SIGA Technologies, is an oral capsule-based antiviral medication with activity against orthopoxviruses, including monkeypox. It has a conditional market authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) for use in England, Scotland and Wales and from the European Medicines Agency (covering its use in Northern Ireland) for the treatment of monkeypox in adults and children with a weight of at least 13kg, as follows:

Body Weight	**Dosage**	**Number of Capsules Per Dose**
13kg to less than 25kg	200mg every 12 hours for 14 days	One tecovirimat 200mg capsule
25kg to less than 40kg	400mg every 12 hours for 14 days	Two tecovirimat 200mg capsules
40kg and above	600mg every 12 hours for 14 days	Three tecovirimat 200mg capsules

Tecovirimat is now being made available for use in the Health Service under an UK-wide interim clinical policy statement as a treatment for symptomatic patients hospitalised due to monkeypox.

Patients hospitalised due to monkeypox are eligible for treatment with tecovirimat if they meet all of the following criteria:

- monkeypox virus infection is confirmed by polymerase chain reaction (PCR) testing

  and

- symptomatic with a syndrome compatible with ongoing monkeypox virus infection

  and

- meeting any of the criteria[1] for severe or complicated disease as outlined below:

    - critical illness where monkeypox virus infection is considered to be a key factor driving the critical condition of the patient
    - intractable pain
    - rectal abscess or fistula formation
    - upper respiratory tract mucocutaneous involvement that is affecting swallowing or airways
    - patient with primary or acquired immunodeficiency, or on immunosuppressive medication as per Green Book definitions

[1]By exception, treatment outside the above "severe" criteria may be used in the context of treating children or to facilitate shortening the duration of infectiousness due to other complex medical needs. Such treatment must be considered and agreed by the appropriate multidisciplinary team.

- ocular or periocular disease o encephalitis, meningitis or other neurological manifestation
- extensive cutaneous disease (for example more than 100 lesions)
- complex genital disease: difficulty passing urine due to swelling or lesions causing direct urinary obstruction

Please see the full policy statement for further details, including cautions and exclusion criteria, and additional supporting information.

Clinicians are actively encouraged to support recruitment of patients with laboratory confirmed monkeypox infection and with active skin or mucosal lesions, but who do not require hospital admission, to the PLATINUM trial. An observational study, MOSAIC, is exploring outcomes of patients with monkeypox infection across Europe.

Further enquiries should in the first instance be directed to your hospital pharmacy team who will escalate issues to the Regional Pharmaceutical Procurement Service or Pharmaceutical Directorate at the Department of Health if required.

Yours sincerely

Prof Sir Michael McBride
Chief Medical Officer

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