Department of Health & Social Care

NHS

Chief Medical Officer Therapeutic Alert

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Tecovirimat as a Treatment for Patients Hospitalised due to Monkeypox Viral Infection

Summary

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 available in the NHS 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
    - ocular or periocular disease
    - 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.

Action

NHS acute trusts / health boards in England, Northern Ireland, Scotland and Wales are asked to:

- Offer tecovirimat to eligible symptomatic hospitalised patients in line with the published UK wide interim clinical policy statement
- 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 health board / trust drugs and therapeutics committee, or equivalent.
- Note that supply will be held by Specialist Regional Adult Infectious Diseases Centres. For hospitalised patients being treated outside one of these centres, including paediatric patients, arrangements will need to be made for the transfer of tecovirimat supply in liaison with a stock holding centre.

[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.

- In England only, specialist regional adult infectious disease centres should register via Blueteq to participate in tecovirimat specific medicine supply arrangements. Blueteq should also then be used by all treating trusts to confirm pre-authorisation for individual patients. In Northern Ireland, supplies will be held in Belfast HSC Trust and will be available for supply to other HSC Trusts, if required. In Scotland, Health Board Directors of Pharmacy should notify NHS National Procurement if they wish to participate. In Wales supplies will be held in Cardiff and Vale University Health Board and will be available for supply to other health boards if required.
- 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
- 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.

Stock Holding Centres

The following centres are anticipated to hold stock of tecovirimat to be used for hospitalised patients eligible under the UK-wide clinical policy statement. Please note that stock-holding centres may be subject to change.

England

- Brighton and Sussex University Hospitals NHS Trust
- Cambridge University Hospitals NHS Foundation Trust
- Chelsea and Westminster Hospital NHS Foundation Trust
- Guy's & St Thomas' NHS Foundation Trust
- Hull University Teaching Hospitals NHS Trust
- Imperial College Healthcare NHS Trust, London
- Leeds Teaching Hospitals NHS Trust
- Liverpool University Hospitals NHS Foundation Trust
- London North West University Healthcare NHS Trust (Northwick Park Hospital)
- Manchester University NHS Foundation Trust
- Nottingham University Hospitals NHS Trust
- North Bristol NHS Trust
- Oxford University Hospitals NHS Foundation Trust
- Royal Free London NHS Foundation Trust
- Sheffield Teaching Hospitals NHS Foundation Trust
- South Tees Hospitals NHS Foundation Trust
- St George's University Hospitals NHS Foundation Trust, London
- The Newcastle upon Tyne Hospitals NHS Foundation Trust
- University College London Hospitals NHS Foundation Trust
- University Hospitals Birmingham NHS Foundation Trust
- University Hospitals Bristol and Weston NHS Foundation
- University Hospitals of Leicester NHS Trust
- University Hospitals of North Midlands NHS Trust (Stoke)

- University Hospitals Plymouth NHS Trust

Northern Ireland

- Belfast Health and Social Care Trust

Scotland

- Western General Hospital, Edinburgh
- Queen Elizabeth University Hospital, Glasgow

Wales

- University Hospital of Wales, Cardiff and Vale University Health Board

Distribution

Adult and Paediatric Specialist Infectious Diseases Centres
All UK NHS Trusts / Health Boards - Trust/Hospital Medical Directors to circulate to dedicated monkeypox service delivery teams, medical and nursing staff managing front line clinical services and adult and paediatric critical care teams
Ambulance Service Providers
Regional Medical Directors
Regional Chief Pharmacists
Lead/Senior Pharmacists and Regional Procurement Pharmacy Leads
Integrated Care Board (ICB) Chief Medical Officers
Integrated Care Board (ICB) Lead Pharmacists

Enquiries

England
Enquiries from NHS trusts in England should in the first instance be directed to the trust pharmacy team who will escalate issues to a specialist regional infectious diseases centre or the regional chief pharmacist / national team if required.

Northern Ireland
Enquiries from hospitals in Northern Ireland 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 Further information can be obtained by contacting RPHPS.Admin@northerntrust.hscni.net

Scotland
In Scotland, hospital pharmacy access to tecovirimat is being managed via the rarely used urgent medicines (RUMM) arrangements. Access arrangements have already been communicated to Directors of Pharmacy. Any enquiries should be directed to NHS National Procurement: nss.nhssmedicineshortages@nhs.scot

Wales

Enquiries from hospitals in Wales should in the first instance be directed to the health board's Chief Pharmacist who will escalate issues to the Pharmacy and Prescribing Team at Welsh Government if required. Enquiries to the Welsh Government should be directed to: Pharmacyand.PrescribingBranch@gov.wales.