Australian Government
Department of Health and Aged Care

Australian Centre for Disease Control

# 2025 Mpox Treatment Guidelines

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# Revision History

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The 2025 revision was initiated after the Mpox CDNA National Guidelines for Public Health Units was revised.

# Disclaimer

These guidelines outline Australia's national human mpox treatment guidelines. The intention of these guidelines is to reflect the current available evidence base. Readers should not rely solely on the information contained within these guidelines. Guideline information is not intended to be a substitute for advice from other relevant sources, including, but not limited to, advice from a public health specialist or other health professional. Clinical judgment and discretion may be required in the interpretation and application of these guidelines. The membership of the Communicable Diseases Network Australia (CDNA) and the Australian Health Protection Committee (AHPC), and the Australian Government as represented by the Department of Health, Disability and Ageing (*Health*) do not warrant or represent that the information contained in these guidelines is accurate, current or complete. CDNA, AHPC and *Health* do not accept any legal liability or responsibility for any loss, damages, costs or expenses incurred by the use of, or reliance on, or interpretation of, the information contained in these guidelines.

# Executive summary

## Guiding principles

- When required, seek expert guidance for the clinical management of human mpox from an infectious diseases and/or sexual health physician. Because most infections caused by monkeypox virus (MPXV) are mild, most patients will not require antiviral treatment. However, patients requiring antiviral treatment for mpox should have it initiated in consultation with an infectious diseases physician and/or a sexual health physician involved in case management.
- In patients who do not require admission to hospital, management should be coordinated with the patient's primary medical practitioner, with input from relevant specialists and public health units.
- Available treatment options remain investigational. Before initiating treatment, it is important to carefully consider the benefits and risks for each patient.

# Purpose of guidelines

The purpose of these guidelines is to outline the current therapeutic options for the management of human MPXV[1] infection. These guidelines will be reviewed as the mpox situation evolves and as therapeutic options change.

# Scope

- This guidance focuses on the off-label treatment options for patients with confirmed mpox.
- This guidance further provides pharmacological options for post-exposure prophylaxis (PEP) in those at elevated risk of severe complications following mpox exposure (e.g., severely immunocompromised).
- This guidance does not elaborate on the diagnostic work-up and clinical management of patients prior to the confirmation of mpox or vaccine-related complication.
- For further information on **diagnostic workflow** see:
    - Public Health Laboratory Network (PHLN) guidance on mpox patient referral, specimen collection and test requesting
    - PHLN Laboratory Case
    - Communicable Diseases Network Australia (CDNA) MPXV surveillance case definition:
- For further information on **vaccination** see**:**
    - Australian Immunisation Handbook (Mpox chapter)
- For further information on **public health response guidance** see:
    - Mpox CDNA National Guidelines for Public Health Units
- For further information on **other resources** see the mpox collection on the Department of Health, Disability and Ageing website.
  *https://www.health.gov.au/resources/collections/monkeypox-mpox-resources*

# Description of mpox

Mpox is an infectious disease caused by MPXV which sits in the species: *Orthopoxvirus monkeypox* (2023 Release, MSL #39) of the *Orthopoxvirus* genus. MPXV is a DNA virus comprising two clades—clade I (formerly known as the Congo Basin clade) and clade II (formerly known as the West African clade), which further divides into subclades IIa and IIb. In 2024, a new subclade of clade I, known as clade Ib, was identified in the central African region.

[1] Mpox is caused by viruses (e.g., monkeypox viruses) in the species *Orthopoxvirus monkeypox* (2023 Release, MSL #39) within the genus *Orthopoxvirus*. Taxonomical constructs follow the traditional binomial approach with genus and species epithets italicised. Virus names are not italicised (Zerbini et al., 2022).

MPXV can be transmitted through contact with infected animals (bites, scratches, animal body fluids or consumption of insufficiently processed animal meat) or through human-to-human contact. Human-to-human transmission generally requires direct skin-to-skin contact or prolonged close contact, such as being face-to-face in close proximity or indirect contact with materials (fomites) such as contaminated sharps (needles and other instruments used to breach the skin or blood vessels) or bed linen (such as shaking bed linen which collects sloughed skin from lesions containing competent MPXV). Such exposures can occur in a range of settings, including in the household, in a healthcare setting or through sexual contact.

Since 1970, cases of mpox have been reported across several countries in the African continent where the disease is endemic. Mpox has been occasionally exported from these countries to other regions. In May 2022, several countries without endemic mpox began reporting cases. These cases occurred in persons with no recent travel history to endemic areas without links to imported animals. As the outbreak grew, the WHO declared it a public health emergency of international concern (PHEIC) on 23 July 2022. Over subsequent months and into 2023, the global outbreak subsided significantly, and on 10 May 2023, the PHEIC was lifted. The global outbreak of mpox, driven by MPXV clade IIb, primarily spread through sexual contact and mainly affected adult gay, bisexual and other men who have sex with men. However, due to the emergence of the new MPXV clade Ib and a resurgence of cases in the African region, a PHEIC was once again declared on 14 August 2024. The second PHEIC was subsequently lifted on 5 September 2025.

While the global mpox outbreak has been associated with MPXV clade IIb, African countries' outbreaks have historically been driven by MPXV clades I and II, with MPXV clade I being considered more virulent than MPXV clade II. In 2023, alongside the reported increase of mpox cases in endemic areas, transmission through sexual contact of the more virulent MPXV clade I was documented for the first time in the DRC and has since been reported in other countries in the region. At that time, outbreaks involving MPXV clade Ib were predominantly characterised by heterosexual transmission linked to commercial sex work, as well as small clusters of cases among men who have sex with men (WHO, 2023).

# Treatment of symptomatic infection

## Treatment Overview

- Mpox is generally a self-limited infection. Most cases will not require specific treatment other than supportive management or treatment of complications (e.g., antibiotics for secondary cellulitis).
- Antiviral therapy should be initiated in consultation with an infectious diseases and/or sexual health physician[2].
- Depending on the presentation and local protocols, patients admitted to a hospital may be managed in a centre with suitable biocontainment care capability[3].

[2] If the outbreak becomes prolonged, clinical management and treatment initiation by primary care medical practitioners (GPs) may become routine.
[3] End to end patient management should be coordinated by a hospital incident management team.

- Outpatient management and shared care with the patient's primary medical practitioner are recommended for clinically well patients.
- Tecovirimat is the preferred treatment for severe mpox.

## Treatment options

Current therapeutic options (Bruno & Buccoliero, 2023; Fox et al., 2023) for human mpox in Australia include:

- Tecovirimat
- Vaccinia immune globulin (VIG)

If expert clinical judgement determines a patient requires specific treatment for mpox, the preferred first option for drug treatment is tecovirimat. If tecovirimat is unavailable, VIG is the next preferred option.

- **Tecovirimat**, which is held in the National Medical Stockpile (NMS), is not approved for the treatment of human mpox by the Therapeutic Goods Administration (TGA)[4] (CDC, 2024a). It appears to be well tolerated and active *in vitro* against orthopoxviruses. It is highly efficacious as PEP and treatment in animal models (ECRAID, 2024; NIAID, 2024; NIHR, 2022; SIGA, 2024; Telford et al., 2023). See appendix for further details.
- **VIG** is held in the NMS in limited quantities. It may need to be used when the safety of Tecovirimat has not been established such as during pregnancy and breastfeeding:

# Other treatments with potential activity

- **Cidofovir**, which is currently TGA registered and used in Australia for the treatment of human cytomegalovirus (CMV) infections, other human herpesvirus, and adenovirus infections in immunocompromised patients. Cidofovir should be carefully considered for the treatment of mpox to preserve supply, particularly for patients with difficult to treat CMV disease and other viral infections in those that have undergone solid organ or hematopoietic stem cell transplantation. The significant adverse events profile, especially nephrotoxicity and myelosuppression, may outweigh the benefit.

## Indications for use in confirmed mpox

- Tecovirimat for 14 days is the preferred treatment of mpox when treatment is deemed necessary. See appendix for dose and route of administration.
- Those who should be considered for treatment may include:
    - Those with severe disease (e.g., haemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalisation)
    - Those who may be at high risk of severe disease:
        - Those who are immunocompromised (e.g., acquired immune deficiency syndrome with CD4 count <200 cells/μL[5] leukaemia, lymphoma,

[4] The Therapeutic Goods Administration has granted an emergency exemption for the medicine Tecovirimat for use in Australia against mpox.
[5] This threshold of 200 cells/μL represents a live vaccine cut-off between a moderate and severe definition of immunocompromise in a setting of HIV infection. This threshold will also balance antiviral supply.

generalised malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumour necrosis factor inhibitors, high-dose corticosteroids, hematopoietic stem cell transplant recipient <24 months post-transplant or ≥24 months but with graft-versus-host disease or disease relapse, or having autoimmune disease with immunodeficiency as a clinical component).
    - Paediatric populations, particularly patients younger than 8 years of age.
    - Persons who are pregnant or breastfeeding (see VIG under Treatment Options).
    - Those with one or more complications (e.g., secondary bacterial skin infection; gastroenteritis with severe nausea/vomiting, diarrhoea, or dehydration; bronchopneumonia; concurrent disease or other comorbidities). Other complications include aberrant infections that include its accidental implantation in eyes, mouth, or other anatomical areas where mpox might constitute a special hazard (e.g., the risk of secondary bacterial infection and Fournier's gangrene in relevant sites where the risk of complicated skin and soft tissue infections are high).
- Early treatment in immunocompromised and other risk groups, e.g., children and pregnant patients. In pregnant patients, consult an infectious diseases physician for the management of pregnant persons. In very young children, consider treatment for confirmed infection with serious or progressive infection. Consult an infectious diseases paediatrician for management of paediatric infections.

# Post-exposure prophylaxis following a significant mpox exposure in an individual at high-risk of complications

## Identifying contacts of confirmed mpox cases

- Identifying contacts for potential PEP will be aided by referring to the Mpox CDNA National Guidelines for Public Health Units.

## PEP overview and options

- There is a role for vaccination as PEP (PEPV). This guideline should be read in conjunction with Australian Immunisation Handbook advice on the use of mpox vaccines for PEP.
- Antiviral agents may be used for PEP. Evidence for the use of antiviral agents is limited.
- Antiviral therapy for PEP should be initiated in consultation with an infectious diseases and/or sexual health physician.
- PEP with Tecovirimat is usually reserved for high-risk, immunocompromised patients and is decided case-by-case, depending on the patient's risk of complications.
- There is no accepted guidance on the dose and duration of Tecovirimat for PEP. The dose and duration will be determined by the clinical needs of the individual requiring antiviral therapy for PEP.

# Accessing the National Medical Stockpile

Any request to access treatments held by the NMS must be made from a state or territory Chief Health Officer (or authorised delegate). Each state and territory has procedural guidance, including relevant forms to complete, on how to access the NMS ahead of the request being e-mailed to the NMS via stockpile.ops@health.gov.au. On receipt of this request, the NMS will seek approval from the Chief Medical Officer for the deployment of the treatments.

# Appendix

***Tecovirimat (NLM, 2024; Russo et al., 2018; Russo et al., 2021)***

| Other names | ST-246, Tpoxx® |
|---|---|
| Dose (treatment) | 200 mg capsules<br>Adult 600 mg bd PO for 14 days; paediatric 13–25 kg: 200 mg bd, 25–40 kg: 400 mg bd, >40 kg: 600 mg bd, with high fat meal<br>No dose adjustments for renal/hepatic failure |
| Regulatory history | Approved by the FDA for treatment of human smallpox disease.<br>Not TGA registered |
| Mechanism of action | Antiviral drug that inhibits the orthopoxvirus VP37 envelope wrapping protein. Prevents the formation of egress competent enveloped virions necessary for cell-to-cell and long-range dissemination of virus. |
| Clinical pharmacology | Resistance: mutations in target VP37. Treatment emergent resistance reported (Lederman et al., 2012).<br>Peak serum concentration of tecovirimat under fed conditions is up to 50% higher than under fasting conditions. |
| Efficacy | Efficacy based on animal studies (95% vs 5% mortality in non-human primates), may be less effective in immunocompromised and if given >6 days after challenge (noting incubation period in animal models are much shorter than in humans so day 4 is approximately the onset of lesions)<br>Potential utility as post-exposure prophylaxis based on animal models, but duration of treatment unclear.<br>Recent PALM 007 trial suggests tecovirimat does not significantly improving the time to lesion resolution compared to a placebo. However, tecovirimat showed potential benefits for patients who received treatment early (within 7 days) and those with severe disease (>100 lesions) (NIH, 2024). |
| Safety | Phase 1 study in humans (n=449, n=359 received active drug) - no safety signals. One fatal AE (PE) not related (Grosenbach et al., 2018).<br>Pregnancy — animal studies - no toxicity. Detectable in breast milk.<br>Common side effects include headache, nausea, abdominal pain, and vomiting. |
| Practice points | Interactions: repaglinide (hypoglycaemia)<br>For patients who have trouble swallowing capsules; capsules can be administered by carefully opening the capsule and mixing the entire contents in 30 mL of liquid (e.g., milk, chocolate milk) or soft food (e.g., apple sauce, yoghurt). The entire mixture should be administered within 30 minutes of its preparation. |

***Vaccinia immune globulin (VIG) (CDC, 2024b; FDA, 2018)***

| Other names | Vaccinia Immune Globulin Intravenous (Human) |
|---|---|
| Proposed dose | Dose of 6000 Units/kg intravenous.<br><br>Consider higher doses where the patient does not respond to the initial dose. Multiple and repeated treatments may be required. |
| Regulatory history | Not TGA registered.<br><br>Indications include:<br><br>- Eczema vaccinatum<br>- Progressive vaccinia<br>- Severe generalised vaccinia<br>- Vaccinia infections in individuals who have skin conditions such as burns, impetigo, varicella-zoster, or poison ivy; or in individuals who have eczematous skin lesions because of either the activity or extensiveness of such lesions<br>- Aberrant infections induced by vaccinia virus that include its accidental implantation in eyes (except in cases of isolated keratitis), mouth, or other areas where vaccinia infection would constitute a special hazard.<br><br>VIG is not considered to be effective in the treatment of postvaccinial encephalitis |
| Clinical pharmacology | VIG provides passive immunity for individuals with complications to vaccinia virus vaccination. The exact mechanism of action is not known<br><br>After intravenous administration of 6000 Units per kg to 31 healthy subjects in a double-blind study, the peak plasma concentration was achieved within 2 hours. The half-life of VIG was 30 days (range of 13 to 67 days) |
| Efficacy | Clinical studies suggest reduced pox reaction and erythema area following VIG administration. |
| Safety | Contraindications:<br><br>- isolated vaccinia keratitis (Altmann et al., 2011).<br>- anaphylaxis or prior severe systemic reaction associated with the parenteral administration of this or other human immune globulin preparations<br>- IgA-deficient patients with antibodies against IgA and a history of IgA hypersensitivity, as it contains trace amounts of IgA.<br><br>Precautions: VIG administration is associated with aseptic meningitis syndrome, transfusion-related acute lung injury, acute renal dysfunction/failure, thrombosis, aseptic meningitis, and haemolysis.<br><br>Common adverse reactions in clinical trials (>10%) include headache, nausea, rigors, and dizziness. |

| Other names | Vaccinia Immune Globulin Intravenous (Human) |
|---|---|
| Practice points | Product may be stored frozen at or below –15 °C or refrigerated at 2–8 °C.<br><br>Bring VIG vials to room temperature prior to dosing. Administer 6000 U/kg intravenously through a dedicated intravenous line with the infusion rate of no greater than 2 mL/min.<br><br>Blood glucose measurement in patients receiving VIG must be done with a glucose-specific method (monitor and test strips) to avoid interference by maltose contained in VIG. Glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ) or glucose-dye-oxidoreductase method (monitor and test strips) must not be used for blood glucose testing in patients receiving VIG, since maltose in VIG products has been shown to give falsely high blood glucose levels in these testing systems. |

***Cidofovir (Stittelaar et al., 2006; TGA, 2019)***

| Other names | Vistide; EMPOVIR |
|---|---|
| Proposed dose | 5 mg/kg body weight, intravenous<br><br>Induction treatment: Intravenous infusion at a constant rate over 1 hr administered once weekly for two consecutive weeks.<br><br>Maintenance treatment: Beginning two weeks after the completion of induction treatment, intravenous infusion at a constant rate over 1 hour administered once every two weeks. |
| Regulatory history | Approved by the TGA for the treatment of CMV infection in adults with acquired immunodeficiency syndrome |
| Clinical pharmacology | Inhibits viral DNA synthesis in CMV<br><br>Half-life elimination: 2.6 hours<br><br>Excretion: urine |
| Efficacy | No clinical data regarding efficacy against mpox in humans<br><br>Significant adverse events, including nephrotoxicity (kidney failure is cited as a common adverse effect in the PI)<br><br>In vitro activity against mpox and has been shown to be effective against lethal challenge in animal models |
| Safety | Contraindications: renal impairment; concomitant administration of cidofovir and potentially nephrotoxic agents (e.g., NSAIDs) |

| | |
|---|---|
| Other names | Vistide; EMPOVIR |
| | Precautions: dose-dependent nephrotoxicity; uveitis and/or iritis; decreased intraocular pressure/ocular hypotony; neutropaenia.<br><br>Pregnancy category D (do not use).<br><br>Common adverse events include renal failure, neutropaenia, iritis, uveitis, ocular hypotony, nausea, vomiting, diarrhoea, asthenia, fever, alopecia, and rash. |
| Practice points | Closely monitor renal function.<br><br>With a syringe, transfer the appropriate dose of Cidofovir (5 mg/kg body weight) from the vial to an infusion bag containing 100 mL 0.9% (normal) saline solution, and mix thoroughly. The entire volume should be infused intravenously into the patient (adult aged 18 years or older) at a constant rate over a period of 1 hour by use of a 2 standard infusion pump.<br><br>Store at a temperature below 25 °C. Do not refrigerate or freeze. Infusion admixtures may be stored temporarily for up to 24 hours in a refrigerator (2–8 °C) when reconstitution is performed under aseptic conditions.<br><br>Administration of Probenecid 2 g *po* 3 hours before Cidofovir, and 1 g 2–8 hours post Cidofovir is recommended for most indications to increase blood levels. Probenecid may interact with several other medications. If probenecid cannot be administered the pharmacokinetics of Cidofovir may be less reliable. |

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