Australian guidelines for the clinical care of people with MPX

Main editor

Australian National Clinical Evidence Taskforce

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National Clinical Evidence Taskforce - MPX

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Disclaimer

The consortium is seeking NHMRC approval of the guideline under section 14A of the National Health and Medical Research Council Act 1992. As part of the approval process (and for the lifetime of the guidelines), public consultation is required. We welcome your feedback and suggestions. Comments can be submitted via the feedback function under each recommendation in MAGICapp or by emailing info@clinicalevidence.net.au.

These clinical guidelines are a general guide to appropriate practice, to be followed subject to the clinician's judgement and the patient's preference in each individual case. The guidelines are not intended to be proscriptive. They are designed to provide information to assist decision making and have been informed by the highest quality evidence available at the time of compilation. Accordingly, the parties involved in the development of these guidelines shall have no liability to any users of the information contained in this publication for any loss or damage, cost or expense incurred or arising from reliance on the information contained in this publication.

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Summary of recommendations

1. Reading Guide

Info Box

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An “only in research settings” recommendation is given when there is insufficient evidence to determine if an intervention is either beneficial or harmful. When an “only in research” recommendation is given, the panel recommends that the intervention should only be considered in a randomised clinical trial with appropriate ethical approval. In any other circumstance, the intervention is not recommended.

Consensus Recommendation (Bluish-Purple)
A consensus recommendation can be given for or against the intervention. This type of recommendation is used when there is not enough evidence to give an evidence-based recommendation, but the panel still regards it as important to give a recommendation.

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2. Introduction

Info Box

Monkeypox (MPX) is a disease caused by infection with the monkeypox virus (MPXV), which is part of the same family of viruses as variola virus (the virus that causes smallpox). MPXV was first detected in humans in 1970 in the Democratic Republic of the Congo and has since been considered endemic within parts of Africa *[1]*.

Since early May 2022, multiple cases of MPX have been reported outside of endemic regions *[1]*. On 23 July 2022, after 3000 cases were reported across 50 countries, the World Health Organization (WHO) declared the escalating global MPX outbreak a Public Health Emergency of International Concern (PHEIC) *[2]*. Shortly thereafter, Australia declared the MPX situation a Communicable Disease Incident of National Significance on 26 July 2022 *[3]*.

As at 20 October, there have been 140 cases (confirmed and probable) of MPX in Australia *[3]* and over 75 000 cases have been recorded worldwide *[4]*.

Symptoms of MPX tend to be self-limiting, lasting from 2 to 4 weeks. However, some people are at increased risk of becoming severely unwell, including young children (< 8 years of age), individuals who are pregnant or immunocompromised, and individuals with history of atopic dermatitis or eczema *[5]*.

Clinical guidelines are integral to ensuring that healthcare decisions are based on the best available evidence. Since the emergence of MPX, some national and international organisations have released guidelines related to different aspects of the management of people with MPX. The National Clinical Evidence Taskforce – MPX was established to develop (in partnership with a range of national professional societies and organisations) living guidelines for clinical management and care of people with suspected or confirmed MPX.

Recommendations within this guideline were developed in collaboration with the organisations listed below. All member organisations are part of the steering committee and formally endorse the guideline. The Steering Committee is governed by a consensus based decision-making process, for more details on the methods and processes of the Taskforce please see the Methods and processes section of this guideline.

Cochrane Australia (Secretariat)

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- Australian and New Zealand College of Anaesthetists
- Australian and New Zealand Intensive Care Society
- Australian and New Zealand Society for Geriatric Medicine
- Australian College of Critical Care Nurses
- Australian College of Midwives
- Australian College of Nursing
- Australian College of Neonatal Nurses
- Australian College of Rural and Remote Medicine
- Australian Primary Health Care Nurses Association
- Australian Resuscitation Council
- Australian Sleep Association
- Australian Society of Anaesthetists
- Australasian Association of Academic Primary Care
- Australasian College for Emergency Medicine
- Australasian College for Infection Prevention and Control
- Australasian College of Paramedicine
- Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine
- Australasian Society for Infectious Diseases
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
- College of Emergency Nursing Australasia
- CRANAplus
- National Aboriginal Community Controlled Health Organisation
- Palliative Care Australia
- Rehabilitation Medicine Society of Australia and New Zealand
- Royal Australasian College of Physicians
- Royal Australasian College of Surgeons
- Royal Australian and New Zealand College of Psychiatrists
- Royal Australian College of General Practitioners
- Society of Hospital Pharmacists of Australia
- Thoracic Society of Australia and New Zealand

- Thrombosis and Haemostasis Society of Australia and New Zealand

3. Methods and processes

Info Box

Methods and processes
Information about the methods used is described in the methods and processes document.

Information about our governance structure and members' details is available here.

Our policy on the use of media statements, preprints and other non-peer-reviewed papers in formulating recommendations is available here.

Conflicts of interest
Our policy for managing conflicts of interest and the template used for collecting the declarations of interest can be found on the website here and here.

Public consultation
We welcome feedback and suggestions. Comments can be submitted via the feedback function under each recommendation in MAGIC or by emailing info@clinicalevidence.net.au.

4. Disease severity and risk of severe disease

Consensus recommendation

Severe MPX disease may present with the following symptoms – skin or mucous membrane lesions which are: extensive, confluent, haemorrhagic, or located where they cause functional impairment or severe pain (e.g. oropharyngeal, anorectal/ proctitis, genital, eyes); internal organ disease (e.g. pneumonitis, encephalitis); complicated disease (e.g. sepsis).

Consensus recommendation

Some people with MPX are at higher risk of developing severe disease, or at higher risk of developing severe consequences as a result of MPX.

These include people with any of the following characteristics:

- immunocompromised (e.g. acquired immune deficiency syndrome with CD4 count < 200 cells/µL8, leukaemia, lymphoma, generalised malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumour necrosis factor inhibitors, high-dose corticosteroids, haematopoietic 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)
- children particularly younger than 8 years of age
- pregnant or breastfeeding
- extensive primary lesions
- lesions in anatomical areas with the potential for development of scarring, strictures or other serious consequences

Consensus recommendation

Mild MPX disease is defined as MPX infection in the absence of symptoms of severe disease.

Mild disease usually lasts 2 to 4 weeks with lymphadenopathy, fever (≥ 38°C) or history of fever, headache, myalgia, arthralgia and back pain in the first 1 to 5 days. A maculopapular rash may develop 1 to 2 days before or 1 to 5 days after the onset of fever, with the lesions typically evolving contemporaneously into vesicles. A small or moderate number of lesions, often in the anogenital area, is common in mild illness in Australia. The rash may be either generalised or localised, and tends to be more concentrated on the face and extremities rather than the trunk.

Mild disease and symptoms usually resolve without the need for specific therapy.

5. Drug treatments

Info Box

Most people with MPX will experience self-limiting mild disease without the need for specific therapies, and will only require supportive care as an outpatient and/or in the community at home.

Mild disease management may involve:

- Antipyretics for fever
- Analgesia for pain
- Adequate nutrition
- Appropriate oral rehydration
- Prevention of constipation
- Keeping skin lesions clean and dry to prevent bacterial infection
- Monitoring skin and lesions for signs of infection and cellulitis
- Appropriate psychological support for their needs

Further guidance will be provided on supportive care; the MPX panel is currently preparing to review the topics listed above.

Recommendations will be published once they are reviewed by the Guidelines Leadership Group and approved by the Steering Committee before publication. In addition, all recommendations are reviewed by the consumer members of the panel to establish acceptability to the patient population for which they are relevant.

5.1 Recommended drug treatments

5.1.1 Tecovirimat

Consensus recommendation

Consider using tecovirimat in individuals with severe MPX, or who are at high risk of severe MPX, or at higher risk of developing severe consequences as a result of MPX.

Remark:
A decision to provide tecovirimat should be based on the individual's disease severity and/or risk factors for severe disease and made in consultation with an infectious diseases and/or sexual health physician with expertise in the management of MPX. The balance of potential benefits and harms of treatment should be discussed with the individual before a decision is made, particularly for people who are pregnant.

Explanation of individuals with severe disease, or at high risk of severe disease, or severe consequences can be found in section 4 – Disease severity and risk of severe disease.

Existing guidelines for the treatment of MPX support the use of tecovirimat in adults with severe disease or with one or more risk factors for severe disease* *[11][12][13]*. Evidence informing this recommendation is limited to observational reports, animal and *in vitro* studies *[6][7][8]*. Currently no randomised trials are available to inform the recommendation; this may change in the future with several trials now registered. Tecovirimat has demonstrated effectiveness in animal models *[7]*, and a randomised placebo-controlled human safety study of 449 healthy volunteers showed similar occurrence of adverse events in both groups *[6]*.

Where possible, treatment should be provided in the context of a randomised trial with appropriate ethical approval. Rigorous data collection should be undertaken on indications and key outcomes for individuals who receive tecovirimat for the treatment of MPX.

Based on existing guidelines, the following dose and regimen is recommended *[11]*:

- Adults and paediatric patients > 40 kg: 600 mg every 12 hours (three 200 mg capsules) for 14 days
- Paediatric patients (13–25 kg): 200 mg every 12 hours (one 200 mg capsule) for 14 days
- Paediatric patients (25–40 kg): 400 mg every 12 hours (two 200 mg capsules) for 14 days

In the absence of reliable evidence, the Taskforce has developed this recommendation based on existing international guidelines combined with their clinical expertise and experience.

Tecovirimat is available within the National Medical Stockpile, however the Therapeutic Goods Administration has not approved the use of tecovirimat for the treatment of MPX within Australia *[11]*.

*Risk factors for severe disease can be found in section 4 – Disease severity and risk of severe disease.

The Taskforce will continue to monitor for further evidence as it emerges and will update this recommendation when definitive evidence becomes available.

5.2 Drug treatments currently under review

Info Box

The Taskforce is currently reviewing drug treatments listed below in individuals with MPX, and recommendations will be published in the near future.

- Brincidofovir (Tembexa)
- Cidofovir (Vistide)
- Vaccinia immune globulin (VIG)

5.2.1 Vaccinia immune globulin (VIG)

5.2.2 Brincidofovir (Tembexa)

5.2.3 Cidofovir (Vistide)

5.2.4 Other drug treatments

6. Supportive care

Info Box

The Taskforce is currently reviewing the aspects of supportive care listed below in individuals with MPX, and recommendations will be published in the near future.

- Nutrition
- Psychosocial support

6.1 Antibiotics

Consensus recommendation New

Do not routinely use antibiotic therapy or prophylaxis in people with uncomplicated MPX.

Consensus recommendation New

Monitor lesions for signs of secondary bacterial infection and, if present, treat with appropriate antibiotics.

Remark:
Educate and support people with MPX to recognise signs and symptoms of secondary bacterial infection of skin lesions and seek immediate consultation with appropriate heath care provider.

In hospital, care should also involve regular assessment of skin lesions by heath care providers to monitor for signs of infection.

6.2 Pain management

Consensus recommendation New

Consider using analgesia to manage pain associated with MPX infection.

Remark:
Pain management should be addressed in all people with MPX infection as substantial pain may result from mucosal lesions. Multimodal analgesic strategies, including the considered use of safely dosed topical local anaesthesia, should be used to manage pain tailored to individual needs

6.3 Nutrition

6.4 Skin and wound care

Consensus recommendation New

Assess skin of people with MPX irrespective of disease severity or treatment location.

Remark:
Educate and support people with MPX to:

- avoid scratching skin
- keep skin lesions clean and dry to prevent bacterial infection
- use hand hygiene with soap and water or alcohol-based hand sanitizer before and after touching the skin rash to prevent infection
- gently clean lesions with clean water
- leave rash uncovered and exposed to open air to dry
- in health care setting or public appropriately cover skin lesion (e.g. low adherent dressings, clothes or gown)

6.5 Psychosocial support

7. Abbreviations and acronyms

Info Box

AHPRA	Australian Health Practitioner Regulation Agency
CI	Confidence interval
GRADE	Grading of recommendations, assessment, development and evaluation
ID	Infectious disease
IQR	Interquartile range
MPX	Monkeypox
MPXV	Monkeypox virus
NCET	National Clinical Evidence Taskforce
NHMRC	National Health and Medical Research Council
NICE	National Institute for Health and Care Excellence
OR	Odds ratio
PHEIC	Public Health Emergency of International Concern
PPE	Personal protective equipment
RR	Risk ratio
TGA	Therapeutic Goods Administration
VIG	Vaccinia immune globulin
WHO	World Health Organization

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Updating and public consultation
Research related to the care of people with MPX is ongoing and will potentially impact clinical recommendations. To ensure these guidelines are updated rapidly in response to new and important evidence, the underpinning knowledge syntheses and recommendations will be reviewed and updated on an ongoing basis. It is anticipated that these living recommendations will be updated weekly as and when new evidence is available. This will be reflected in the publication of a new version in which changes made to a specific recommendation or supporting information are highlighted in order to emphasise the update.

The Taskforce will seek NHMRC approval of the guideline under section 14A of the *National Health and Medical Research Council Act 1992* on an ongoing basis as new recommendations are added or existing recommendations are changed. As part of the approval process (and for the lifetime of the guidelines), public consultation is required. We welcome your feedback and suggestions. Comments can be submitted via the feedback function under each recommendation in MAGIC, see the reading guide in the above section for guidance, or by emailing info@clinicalevidence.net.au.

Purpose
The purpose of this guideline is to provide health professionals and patients with up-to-date, evidence-based recommendations to guide shared decision-making in the treatment of MPX. The guideline contains specific and actionable recommendations for selected, well-defined clinical problems (i.e. what needs to be done and who it is relevant to). It does not define the individuals responsible for providing care, nor does it consider the social or economic implications of guideline adherence.

Scope
This guideline aims to provide specific, patient-focused recommendations on management and care of people with suspected or confirmed MPX. With the exception of chemoprophylaxis for the prevention of infection in people exposed to MPX, the guideline does not include other interventions used in the prevention of MPX infection or transmission. Within each recommendation, the patient population of interest is specified.

Consumer-centred care in the context of MPX
Consumer-centred care is the provision of health care that is respectful of, or responsive to, the needs, preferences and values of consumers. Consumer-centred care "*...redefines the relationships in health care by placing an emphasis on collaborating with people of all ages, at all levels of care, and in all health care settings.*" *[5][14]*

The key principles of consumer-centred care include:

- respect for patients' preferences and values
- emotional support
- physical comfort
- information, communication and education
- continuity and transition
- coordination of care
- involvement of family and friends
- access to care *[6]*

The Taskforce recognises that actively addressing issues of equity, diversity and inclusion is vital to ensure all individuals and communities in Australia experience good quality health care and health outcomes.In addition to traditional clinical risk factors, the health of individuals and communities are influenced by sex, gender, sexuality, ethnicity, migrant status, disability, language, education, income, employment, power, geographical location and social support. These factors are often interconnected and interact at macro levels with a compounding effect to produce a broad range of unequal health outcomes. This concept is referred to as "intersectionality".

The Australian Charter of Healthcare Rights (2nd edition) outlines the basic rights that patients and consumers are entitled to receive. These rights are particularly important in the current context. Rights of particular note include:

- access to healthcare services and treatment that meet needs
- safety through safe and high-quality health care in an environment that feels safe

- respect as an individual, with culture, identity, beliefs and choices recognised
- partnership through open and honest communication with healthcare providers
- information about their conditions and the possible benefits and risks of different tests and treatments, waiting times and costs and access to health information to support informed consent
- privacy and security of personal and health information maintained *[15]*

MPX requires clinical responsiveness to new and emerging treatments, including a significant degree of uncertainty as new treatments emerge. However, consumer preferences and values must remain central in the provision of healthcare and be balanced with the needs of the health service and public health concerns. Health services remain responsible for ensuring that their work remains patient centred. In the context of MPX, key concepts include ensuring:

- equity in resource allocation and provision of care
- choice and agency of the consumer
- ethical provision of care at all times

Informed consent is a further component of consumer-centred care and underpins consideration of treatment options for MPX by consumers, families and carers.

Informed consent
Informed consent forms an essential component of the moral right of individuals to autonomy over their own bodies *[9]*. Informed consent is generally understood to be a person's voluntary decision about their health care that is made with knowledge and understanding of the benefits and risks involved *[16][17]*.

In practical terms, informed consent is the process by which a healthcare professional provides appropriate information to a consumer about their treatment options, associated risks and benefits, fees, charges and possible additional costs, and supports them to make a decision about their care. From a legal perspective, informed consent should comply with jurisdictional legislation and best practice and is defined in terms of an agreement or process by which, having provided the relevant information, the rights of individuals to agree or to refuse treatment are upheld. This is particularly important where there are issues relating to impaired capacity of a person to consent *[16]*.

Consent processes help deliver services that are more closely aligned with the priorities and concerns of the community. This has a range of benefits, including improved health outcomes and a more efficient allocation of resources. In this way, informed consent processes are important in developing a genuinely consumer-focused health system.

For ethical decision-making, decisions about whether care is provided and in what form must be informed by the preferences of patients as well as clinical judgement *[9]*. Any changes affecting the existing plan or access to treatment must be considered with the patient, and the consented plan drafted and followed.

The *National Health and Medical Research Council (NHMRC) Guidelines: Communicating with Patients* addresses the content of information that should be provided, and states the patient needs to be advised of the possible or likely nature of the procedure or treatment [and] the proposed approach, including:

- what the proposed approach entails
- the expected benefits
- common side effects and material risks
- whether the procedure is conventional or experimental
- who will perform the procedure or treatment
- other options for management of the complaint
- the realistic expectations for the outcome of the procedure or treatment
- the time and cost involved, including any out-of-pocket expenses and any potential costs should further treatment be required *[18]*

These principles underpin the Australian Health Practitioner Regulation Agency (AHPRA) standards for healthcare professionals, including medical and allied health practitioners, and nurses and midwives to support informed consent by patients about their health care *[17]*.

While in the context of MPX, decisions may be being made at greater speed and in more resource-constrained environments than other health care environments, efforts must be made as far as practical to ensure that consumers are involved in their care.

In practical terms, informed consent processes should support the role of consumers as genuine partners in health care and promote consumer involvement in decision-making. Shared decision-making practices as between a treating team and consumer (patients as partners in care) should be standard practice. Consideration must be paid to people with complex communication needs, including those who communicate in ways other than speech and have limited capacity to make decisions about their health care. All consumers should be actively involved in decisions about their treatment and care to the extent they wish to be, and they should be supported to do so *[19]*.

Note on the language in the pregnancy and perinatal care recommendations
The Taskforce recognises that individuals have diverse gender identities. Terms such as *pregnant person*, *childbearing people* and *parent* can be used to avoid gendering birth, and those who give birth, as feminine. We use these words to be inclusive of all people who are pregnant or breastfeeding.

Target audience
These recommendations are applicable to individuals responsible for the care of people with MPX. These include health professionals, individuals providing support and education to people with MPX, and people with diagnosed or suspected MPX themselves.

Individuals such as policymakers, practice managers, researchers and students may elect to use or adopt these recommendations for purposes other than the treatment of MPX; however these individuals do not represent the target audience. Additional considerations not addressed within this guideline are required when using these recommendations for any purpose other than for the treatment or support of individuals with MPX.

3. Methods and processes

TBA

Info Box

Methods and processes
Information about the methods used is described in the methods and processes document.

Information about our governance structure and members' details is available here.

Our policy on the use of media statements, preprints and other non-peer-reviewed papers in formulating recommendations is available here.

Conflicts of interest
Our policy for managing conflicts of interest and the template used for collecting the declarations of interest can be found on the website here and here.

Public consultation
We welcome feedback and suggestions. Comments can be submitted via the feedback function under each recommendation in MAGIC or by emailing info@clinicalevidence.net.au.

4. Disease severity and risk of severe disease

Consensus recommendation

Severe MPX disease may present with the following symptoms – skin or mucous membrane lesions which are: extensive, confluent, haemorrhagic, or located where they cause functional impairment or severe pain (e.g. oropharyngeal, anorectal/proctitis, genital, eyes); internal organ disease (e.g. pneumonitis, encephalitis); complicated disease (e.g. sepsis).

Consensus recommendation

Some people with MPX are at higher risk of developing severe disease, or at higher risk of developing severe consequences as a result of MPX.

These include people with any of the following characteristics:

- immunocompromised (e.g. acquired immune deficiency syndrome with CD4 count < 200 cells/µL8, leukaemia, lymphoma, generalised malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumour necrosis factor inhibitors, high-dose corticosteroids, haematopoietic 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)
- children particularly younger than 8 years of age
- pregnant or breastfeeding
- extensive primary lesions
- lesions in anatomical areas with the potential for development of scarring, strictures or other serious consequences

Consensus recommendation

Mild MPX disease is defined as MPX infection in the absence of symptoms of severe disease.

Mild disease usually lasts 2 to 4 weeks with lymphadenopathy, fever (≥ 38°C) or history of fever, headache, myalgia, arthralgia and back pain in the first 1 to 5 days. A maculopapular rash may develop 1 to 2 days before or 1 to 5 days after the onset of fever, with the lesions typically evolving contemporaneously into vesicles. A small or moderate number of lesions, often in the anogenital area, is common in mild illness in Australia. The rash may be either generalised or localised, and tends to be more concentrated on the face and extremities rather than the trunk.

Mild disease and symptoms usually resolve without the need for specific therapy.

5. Drug treatments

Info Box

Most people with MPX will experience self-limiting mild disease without the need for specific therapies, and will only require supportive care as an outpatient and/or in the community at home.

Mild disease management may involve:

- Antipyretics for fever
- Analgesia for pain
- Adequate nutrition
- Appropriate oral rehydration
- Prevention of constipation
- Keeping skin lesions clean and dry to prevent bacterial infection
- Monitoring skin and lesions for signs of infection and cellulitis
- Appropriate psychological support for their needs

Further guidance will be provided on supportive care; the MPX panel is currently preparing to review the topics listed above.

Recommendations will be published once they are reviewed by the Guidelines Leadership Group and approved by the Steering Committee before publication. In addition, all recommendations are reviewed by the consumer members of the panel to establish acceptability to the patient population for which they are relevant.

5.1 Recommended drug treatments

5.1.1 Tecovirimat

Consensus recommendation

Consider using tecovirimat in individuals with severe MPX, or who are at high risk of severe MPX, or at higher risk of developing severe consequences as a result of MPX.

A decision to provide tecovirimat should be based on the individual's disease severity and/or risk factors for severe disease and made in consultation with an infectious diseases and/or sexual health physician with expertise in the management of MPX. The balance of potential benefits and harms of treatment should be discussed with the individual before a decision is made, particularly for people who are pregnant.

Explanation of individuals with severe disease, or at high risk of severe disease, or severe consequences can be found in section 4 – Disease severity and risk of severe disease.

Existing guidelines for the treatment of MPX support the use of tecovirimat in adults with severe disease or with one or more risk factors for severe disease [11][12][13]. Evidence informing this recommendation is limited to observational reports, animal and in vitro studies [6][7][8]. Currently no randomised trials are available to inform the recommendation; this may change in the future with several trials now registered. Tecovirimat has demonstrated effectiveness in animal models [7], and a randomised placebo-controlled human safety study of 449 healthy volunteers showed similar occurrence of adverse events in both groups [6].*

Where possible, treatment should be provided in the context of a randomised trial with appropriate ethical approval. Rigorous data collection should be undertaken on indications and key outcomes for individuals who receive tecovirimat for the treatment of MPX.

Based on existing guidelines, the following dose and regimen is recommended [11]:

- *Adults and paediatric patients > 40 kg: 600 mg every 12 hours (three 200 mg capsules) for 14 days*
- *Paediatric patients (13–25 kg): 200 mg every 12 hours (one 200 mg capsule) for 14 days*
- *Paediatric patients (25–40 kg): 400 mg every 12 hours (two 200 mg capsules) for 14 days*

In the absence of reliable evidence, the Taskforce has developed this recommendation based on existing international guidelines combined with their clinical expertise and experience.

Tecovirimat is available within the National Medical Stockpile, however the Therapeutic Goods Administration has not approved the use of tecovirimat for the treatment of MPX within Australia [11].

**Risk factors for severe disease can be found in section 4 – Disease severity and risk of severe disease.*

The Taskforce will continue to monitor for further evidence as it emerges and will update this recommendation when definitive evidence becomes available.

Evidence To Decision

Benefits and harms

There are currently no randomised control data to inform benefits and harms, significant uncertainty remains. Although safety and tolerability information is derived from a single randomised placebo control trial in health volunteers and appears well tolerated. In vitro studies show activity against othropoxviruses.

Certainty of the Evidence

There are currently no randomised control data to inform our recommendation, significant uncertainty remains.

Values and preferences

Substantial variability is expected or uncertain

There is no systematically collected information regarding patients' preferences and values at this point. The panel believes that since there is uncertainty regarding the benefit to harm ratio, some patients might think it is better to wait while other patients might be more willing to take risks.

Resources Important issues, or potential issues not investigated

We have no systematically collected evidence regarding cost-benefit. Depending on the treatment, not only should the cost and resource implications be considered but also the potential impact on reduced access to the treatments by patients currently using them for other indications.

Equity Important issues, or potential issues not investigated

There is a risk of creating inequity as some populations are currently not eligible to be enrolled in trials and some will live in geographic areas where opportunities for enrolment are limited or non-existent. Because the benefit to harm ratio is uncertain, it is worth noting that this recommendation will protect more vulnerable populations, such as children.

Acceptability Important issues, or potential issues not investigated

The treatment is probably acceptable to both patients and clinicians. However, we have however no systematically collected evidence regarding acceptability.

Feasibility Important issues, or potential issues not investigated

The implement ability of the recommendation is limited by the fact that not all populations are eligible to be enroled in trials and some will live in geographic areas where opportunities for enrolment are limited or non-existent.

5.2 Drug treatments currently under review

We continually monitor new research for randomised trials that evaluate any treatments for MPX. As each new trial is published, our panels assess and make recommendations on whether the treatment should be used in the clinical care of patients.

For many of these, there is no or insufficient data to determine whether they are safe and/or effective in treating MPX. As a result, the Taskforce has recommended that these treatments are not used to treat MPX until more definitive evidence is available, except where indicated for conditions other than MPX or in the context of a randomised clinical trail. For further information regarding these treatments and the evidence base underlying the recommendation, please click on the treatment of interest below.

Info Box

The Taskforce is currently reviewing drug treatments listed below in individuals with MPX, and recommendations will be published in the near future.

- Brincidofovir (Tembexa)
- Cidofovir (Vistide)
- Vaccinia immune globulin (VIG)

5.2.1 Vaccinia immune globulin (VIG)

5.2.2 Brincidofovir (Tembexa)

5.2.3 Cidofovir (Vistide)

5.2.4 Other drug treatments

6. Supportive care

Info Box

The Taskforce is currently reviewing the aspects of supportive care listed below in individuals with MPX, and recommendations will be published in the near future.

- Nutrition
- Psychosocial support

6.1 Antibiotics

Consensus recommendation

New

Do not routinely use antibiotic therapy or prophylaxis in people with uncomplicated MPX.

Consensus recommendation

New

Monitor lesions for signs of secondary bacterial infection and, if present, treat with appropriate antibiotics.

Educate and support people with MPX to recognise signs and symptoms of secondary bacterial infection of skin lesions and seek immediate consultation with appropriate heath care provider.

In hospital, care should also involve regular assessment of skin lesions by heath care providers to monitor for signs of infection.

6.2 Pain management

Consensus recommendation

New

Consider using analgesia to manage pain associated with MPX infection.

Pain management should be addressed in all people with MPX infection as substantial pain may result from mucosal lesions. Multimodal analgesic strategies, including the considered use of safely dosed topical local anaesthesia, should be used to manage pain tailored to individual needs

6.3 Nutrition

6.4 Skin and wound care

Consensus recommendation

New

Assess skin of people with MPX irrespective of disease severity or treatment location.

Educate and support people with MPX to:

- *avoid scratching skin*
- *keep skin lesions clean and dry to prevent bacterial infection*
- *use hand hygiene with soap and water or alcohol-based hand sanitizer before and after touching the skin rash to prevent infection*
- *gently clean lesions with clean water*
- *leave rash uncovered and exposed to open air to dry*
- *in health care setting or public appropriately cover skin lesion (e.g. low adherent dressings, clothes or gown)*

6.5 Psychosocial support

7. Abbreviations and acronyms

TBA

Info Box

AHPRA	Australian Health Practitioner Regulation Agency
CI	Confidence interval
GRADE	Grading of recommendations, assessment, development and evaluation
ID	Infectious disease
IQR	Interquartile range
MPX	Monkeypox
MPXV	Monkeypox virus
NCET	National Clinical Evidence Taskforce
NHMRC	National Health and Medical Research Council
NICE	National Institute for Health and Care Excellence
OR	Odds ratio
PHEIC	Public Health Emergency of International Concern
PPE	Personal protective equipment
RR	Risk ratio
TGA	Therapeutic Goods Administration
VIG	Vaccinia immune globulin
WHO	World Health Organization

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