Saudi MoH Protocol for Patients Suspected/Confirmed with Mpox

Supportive care and antiviral treatment of suspected or confirmed with Mpox

(Version 1.2) September 11, 2024

Disclaimer: This is a living guidance that is subject to change as more evidence accumulates. It will be updated regularly and whenever needed. The guidance should be used to assist healthcare practitioners select the best available pharmacotherapy for Mpox infection according the best available and current evidence and is not intended to replace clinical judgement but rather to complement it. The evidence is inconclusive regarding the efficacy of most medications for Mpox. It is important to explain this to patient and family and obtain informed consent for use of these medications for unapproved indications.

Mpox Classification†	Supportive Care	Pharmacotherapy	Precautions
Suspected*: Patients presenting with an unexplained acute rash **and** ≥2 of the following signs or symptoms [headache, acute onset of fever (>38.5ºC), lymphadenopathy, myalgia, back pain, or asthenia] **Probable**: Patients fulfilling the definition for a suspected case **and** ≥1 of the following: face-to-face exposure, direct physical contact with skin/skin lesions, reported travel history to an endemic country, positive result of an *orthopoxvirus* serological assay, or hospitalized due to the illness **Confirmed**: Patients fulfilling the suspected or probable case definition **and**	**Skin rash/ulcers:** 1. Keep clean with topical antiseptic 2. Cover with light dressing if extensive skin rash 3. Patients are encouraged not to touch or scratch the lesions 4. Warm saline sitz bath (for vulvovagina ulcers) 5. Gauze dressing impregnated with antibiotic **Oral sores:** 1. Warm saline gurgle 2. Vitamin C and other multivitamins **Conjunctivitis:** 1. Most cases are self-limiting 2. Consult Ophthalmologist if severe or symptoms persist **Dehydration:** 1. Give ORS in mild cases, especially in children 2. Give intravenous fluids (normal saline or dextrose saline as necessary)	**Antivirals:** – **Brincidofovir:** (once available) ○ Adults and pediatrics (≥10 kg): to be given day 1 and 8 • <48 kg: Oral: 4 mg/kg once weekly • ≥48 kg: Oral: 200 mg once weekly ○ Pediatrics (<10 kg): to be given day 1 and 8 • <10 kg: Oral: 6 mg/kg once weekly Criteria for using antivirals: 1. Probable cases (decision of continuing therapy should be based on PCR results) 2. PCR positive confirmed cases 3. Start brincidofovir according to availability within 72 hours of establishing diagnosis.	**Brincidofovir** see below table *"Medication Related Information"* – Increased risk for mortality when used for longer duration – Do not co-administer with IV cidofovir; brincidofovir is a lipid-linked derivative of cidofovir that is intracellularly converted to cidofovir
		Vaccinia immune globulin (SPIG) ○ ≥16 years of age: • IV: 6,000 units/kg as soon as symptoms appear; may repeat dose based on severity of symptoms and response to treatment • 9,000 units/kg may be considered if patient does not respond to initial dose • Single doses up to 24,000 unit/kg were tolerated in healthy volunteers. Note: Maximum dose for patients with risk factors for thrombosis: 12,000 units/kg/day Criteria for using SPIG: 1. Severe PCR positive confirmed cases in combination with antiviral therapy 2. In case of unavailability of antivirals	**Vaccinia immune globulin** see below table *"Medication Related Information"* – Blood glucose measurement – Anaphylaxis/hypersensitivity reactions – Aseptic meningitis – Hemolysis – Pulmonary edema – Thrombotic events

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Laboratory confirmation (Mpox PCR positive **OR** Isolation of Mpox virus in culture)	**High grade fever, pain, or headache:** Start antipyretics **Itching/Pruritus:** 1. Warm bath/warm clothing 2. Calamine lotion 3. Antihistamines **Nausea and persistent vomiting:** Consider antiemetics **Malaise:** 1. Ensure adequate hydration, nutrition 2. Treatment of secondary infection **Poor appetite:** Ensure adequate feeding		

NOTES:

† Please refer to MOH Public Health Authority Interim Guidelines for Mpox last update

* It is not necessary to obtain negative laboratory results for other common causes of rash illness to classify a case as suspected

brincidofovir, and SPIG are not approved by SFDA

Abbreviations:

IV: Intravenous, NS: Normal Saline, ORS: Oral Rehydration Solution, PCR: Polymerase Chain Reaction, SPIG: SmallPox Immune Globulin

Medication Related Information				
Medication	**Contraindication**	**Major Drug Interactions**	**Required dose adjustment**	**Pregnancy and Lactation**
Brincidofovir	– There are no contraindications listed	– Monitor therapy: Cabozantinib, Corticosteroids, Immunosuppressants, Methotrexate, Smallpox and Mpox Vaccine, and Voclosporin – Avoid combination: Cladribine	– Hepatic impairment during treatment → discontinuation if ALT levels remain persistently >10 × ULN – Do not administer second (final) dose on day 8 if ALT elevation is accompanied by clinical signs and symptoms of liver inflammation or increasing direct bilirubin, alkaline phosphatase, or INR – If severe GI adverse events occur, including diarrhea and dehydration, consider discontinuing therapy	– Pregnancy testing is recommended prior to use in patients who may become pregnant – Should use effective contraception during therapy and for at least 2 months after the last brincidofovir dose – Not be used in pregnancy – Not known if it is present in breast milk
Vaccinia immune globulin	– Isolated vaccinia keratitis – History of anaphylaxis or prior severe systemic reaction associated with the parenteral administration of VIGIV or other human immune globulin preparations – IgA-deficient patients with antibodies against IgA and a history of IgA hypersensitivity	– Monitor therapy: Efgartigimod Alfa – Consider therapy modification: Vaccines (Live)	– No dosage adjustment necessary	– No adequate studies in pregnancy

Drug Administration		
Drug	**Formulation**	**Remarks**
Brincidofovir	Tablet and suspension	– Due to carcinogenic potential, avoid direct contact with broken or crushed tablets and oral suspension – Administer on an empty stomach or with a low-fat meal – Swallow tablet whole; do not crush or divide – Shake oral suspension before use
Vaccinia immune globulin	Solution for injection	– For IV infusion only – May be administered undiluted or diluted – Do not exceed recommended rates of infusion – Patients ≥50 kg: Infuse at ≤2 mL/minute; Patients <50 kg: Infuse at ≤0.04 mL/kg/minute. Maximum rate of infusion: 2 mL/minute. – Decrease rate of infusion in patients who develop minor adverse reactions (eg, flushing) and in patients with risk factors for thrombosis/thromboembolism.

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