From

Director General Health Services Haryana, Panchkula

То

Keepers of all Medical Colleges/ Hospitals in Haryana, providing COVID-19 related treatment

Memo.No12/3- MSD (COVID)/ 2021/ 1680 - 1879

Date: 17.05.2021

Subject:- Guidelines regarding distribution of Inj. Amphotericin B available in the State to individual COVID patient.

On the subject cited above,

As you are aware that there is a sudden spurt in Mucormycosis in COVID and Post-COVID patients and there is huge demand of **Inj. Amphotericin B.** An Expert Committee has been constituted to decide on the distribution of Inj. Amphotericin B available in the state of Haryana to individual patient in public/private institutions. The Committee has formulated objective criterion to decide these cases.

The Committee has prescribed the steps to approve Injection Amphotericin B for the treatment of patients, as follows:

- 1. Application: All the COVID Hospitals requiring injection Amphotericin B for treatment of patients shall apply to the Committee on e-mail amphobharyana@gmail.com before 9 AM daily.
- 2. The application will be on the Proforma (Annexure-A). No application without filled Proforma or incomplete Proforma will be entertained. The Proforma must be duly signed by the treating Physician and counter signed by MS of the institution.
- 3. The treating Physician must ensure that the information showing comparative value of Lab tests and conditions of patient must justify use of injection as per approved treatment protocol of GoI/ ICMR (Annexure-B).
- 4. Technical Committee will meet once daily (including holidays) at 12:00 Noon, O/o DGHS must have staff (already assigned) on duty for the same on all days.
- 5. The information about process of applying, Proforma to be filled, process of depositing payment with Civil Surgeons in SKS account and issuing of injection to indenting Hospital is attached with the circular and should be made available on website of Health Department, Haryana.

- 6. The Hospital must apply on official e-mail <u>amphobharyana@gmail.com</u> only. No request should be sent to personal e-mail of the Committee members/ Officers or sent by whatsapp on their mobile numbers.
- 7. The Hospital shall send a single e-mail each day with fully filled Proforma for each case individually for all the patients admitted in their hospital who requires Inj. Amphotericin B. the e-mail must reach everyday before 9:00 A.M.
- 8. After Injection is approved and has been used on patients, the indenting Hospital should give utilization Certificate (UC) of each case and mention the outcome of each case (improved/status quo/deterioration/ died/Any other). This information must be sent to respective CS office/ Nodal Person of the district within 10 days of issue of injection and subsequently on completion of the Treatment . This shall help us in reviewing case selection & therapeutic benefit of Inj. Amphotericin B on patients. In case, an injection has been allotted by the committee for use on patient and has been procured by the indenting hospital from the store and could not be used on same patient because of death or worsening of clinical condition, the same may be re-appropriated for use on next approved patient. The information regarding reappropriation of the said injection on next patient should be communicated to the CS within 10 days of utilization. If said injection is not used within next 10 days, it should be returned to concerned CS so that it can be used on needy patients. This system is put in place to ensure judicious use of injection on needy patient, saving time and to prevent wastage of Injection.
- 9. The letter of issue of approval shall have the following format. this format should be conveyed to all the stakeholders, so that they submit complete information & know that insufficient information shall invite denial of issue of injection.

Ş.	Name	Age/Sex	UHID	Hospital	Proforma	Proforma	Comments
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The O/o DGHS shall compile and present list of all applications received before 9:00 AM on that day to the committee at 12:00 Noon on the same day.

The committee shall assess the cases and convey the decision to O/o DGHS. List of approved cases shall be informed to O/o DGHS. The O/o DGHS shall compile the letter on the approved format as per format above and intimate the same to concerned Civil Surgeon & Stake holders of Private Medical College/Hospitals in Haryana.

- 10. The supply to private institutions would be on actual cost, as procured and informed by HMSCL. The amount shall be reimbursed and deposited in SKS account of concerned Civil Surgeon. However, for all Govt. institutions (Medical Colleges & Hospitals) it would be provided free of cost. The drug would be indented by CS & issued to concerned Health facility after approval of committee.
- Government and Private Medical Colleges will get the said injection from PGIMS, Rohtak and Private Medical Colleges will deposit the requisite amount (actual cost of injection) of said injection into the SKS account of Concerned Civil Surgeon of District.
- 12. Government and Private Hospitals will get the said injection from concerned Civil Surgeon and Private Hospitals will deposit the requisite amount(actual cost of injection) of said injection into the SKS account of Concerned Civil Surgeon of District.
- 13. HMSCL representative must inform about the status of stock position of the Inj. Amphotericin B, the strength and concentration of the injection should be mentioned along with. The stock position should be updated every day by sending an e-mail to O/o DGHS and message on WhatsApp group.
- 14. HMSCL & CS must have staff on duty for depositing cost of injection & issuing of injection 24X7 on all days.
- 15. O/o DGHS will convene the meeting and coordinate with Expert Committee and facilitate the rapid decision making as time is essence, and also monitor overall management of Injection from approval till delivery to concerned hospital, will maintain all the record.

Director Health Services (HMD) for Director General Health Services, Haryana

Endst No. MSD/2021/ 1880- 1938

Date: 17.05.2021

A copy is forwarded to the following for necessary action:-

- 1. Additional Chief secretary to Government of Haryana (MER)
- 2. APS/Hon'ble Chief Minister, Haryana
- 3. Managing Director, HMSCL, Haryana
- 4. Mission Director, National Health Mission, Haryana
- 5. All Deputy Commissioners of the State.
- 6. All the Civil Surgeon of State
- 7. DD (IT) O/o DGHS with a request to publish the same on website of Health Department.
- 8. PS to Hon'ble Health Minister, Haryana.
- 9. PS to Chief Secretary to Govt. of Haryana.
- 10. PS to Additional Chief Secretary to Govt of Haryana (Health)
- 11. Expert Committee constituted vide office order no. 12/3- MSD(COVID)/2021/1626-79 dated 17.05.2021.

Director Health Services (HMD) for Director General Health Services, Haryana

Annexure A

Government of Haryana

Department of Health & Family Welfare

SOPs for Technical Board to decide about Inj Amphotericin B

The following parameters have to be considered and recorded:

Condition	Yes/No	Condition	Yes / No
Recent or Past history of infection with Covid 19		Co existent infection other than Covid	
Nasal Blockage/Facial pain/stuffiness/Blood stained discharge		H/o Diabetes	
Doublevision/Proptosis/Chemosis/cellulitis/diminution of vision		Diabetic Ketoacidosis	4
Blackish Patches over cheek, nose or palate		H/o Steroid intake	
Loosening of teeth or palatal perforation/Halitosis	10.00	H/o intake of Oxygen therapy /BIPAP/HFNC during Covid 19 treatment	
Altered consciousness/seizures/worsening headache	der and -	Renal functions impairment	
Patient on chemotherapy/HIV		h/o Inj Tocilizumab	
		H/o Voriconazole intake	

Investigations	Result
Histopathology of nasal endoscopy guided nasal swab or orbital tissue.	
Direct Microscopy (KOH mount)	
Contrast enhanced MRI/CT	
Surgical findings, if any	

This is certified that:

Mr/Ms/Mrs	S/D/W/o
Age & Sex Address	
ADHAAR	
Institution	City
Hospital UHIDDOADOA eligible candidate for Inj Amphotericin B	

Treating hospital contact person

Name			
	Contact Number	Email	
		E mail	

Treating Physician/Surgeon/ ENT SPECIALIST

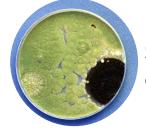
Medical Superintendent

EVIDENCE BASED ADVISORY IN THE TIME OF COVID-19 (Screening, Diagnosis & Management of Mucormycosis)

Mucormycosis - if uncared for - may turn fatal

Mucormycosis is a fungal infection that mainly affects people who are on medication for other health problems that reduces their ability to fight environmental pathogens.





Sinuses or lungs of such individuals get affected after fungal spores are inhaled from the air.

This can lead to serious disease with warning sign and symptoms as follows:

- Pain and redness around eyes and/or nose
- Fever
- Headache
- Coughing
- Shortness of breath
- Bloody vomits
- Altered mental status

What predisposes

- Uncontrolled diabetes mellitus
- Immunosuppression by steroids
- Prolonged ICU stay
- Co-morbidities post transplant/malignancy
- Voriconazole therapy

How to prevent

- Use masks if you are visiting dusty construction sites
- Wear shoes, long trousers, long sleeve shirts and gloves while handling soil (gardening), moss or manure
- Maintain personal hygiene including thorough scrub bath

When to Suspect

(in COVID-19 patients, diabetics or immunosuppressed indiviuals)

- Sinusitis nasal blockade or congestion, nasal discharge (blackish/bloody), local pain on the cheek bone
- One sided facial pain, numbress or swelling
- Blackish discoloration over bridge of nose/palate
- Toothache, loosening of teeth, jaw involvement
- Blurred or double vision with pain; fever, skin lesion; thrombosis & necrosis (eschar)
- Chest pain, pleural effusion, haemoptysis, worsening of respiratory symptoms

Dos

- Control hyperglycemia
- Monitor blood glucose level post COVID-19 discharge and also in diabetics
- Use steroid judiciously correct timing, correct dose and duration
- Use clean, sterile water for humidifiers during oxygen therapy
- Use antibiotics/antifungals judiciously

Don'ts

- Do not miss warning signs and symptoms
- Do not consider all the cases with blocked nose as cases of bacterial sinusitis, particularly in the context of immunosuppression and/or COVID-19 patients on immunomodulators
- Do not hesitate to seek aggressive investigations, as appropriate (KOH staining & microscopy, culture, MALDI-TOF), for detecting fungal etiology
- Do not lose crucial time to initiate treatment for mucormycosis

How to manage

- Control diabetes and diabetic ketoacidosis • Reduce steroids (if patient is still on) with aim to
- discontinue rapidly
- Discontinue immunomodulating drugs
- No antifungal prophylaxis needed
- Extensive Surgical Debridement to remove all necrotic materials
- Medical treatment
 - Install peripherally inserted central catheter (PICC line)
 - Maintain adequate systemic hydration Infuse Normal saline IV before Amphotericin B
 - infusion
 - Antifungal Therapy, for at least 4-6 weeks (see the guidelines below)
- Monitor patients clinically and with radio-imaging for response and to detect disease progression





Team Approach Works Best

- Microbiologist
- Internal Medicine Specialist
- Intensivist
- Neurologist
- ENT Specialist
- Ophthalmologist
- Dentist
- Surgeon (maxillofacial/plastic)
- Biochemist

Detailed management guideline & information available on the following

Global guideline for the diagnosis and management of mucormycosis: an initiative of the European Confederation of Medical Mycology in cooperation with the Mycoses Study Group Education and Research Consortium. Lancet Infect Dis. 2019 Dec;19(12):e405-e421. doi: 10.1016/S1473-3099(19)30312-3.

https://www.ijmr.org.in/temp/IndianJMedRes1533311-<u>3965147 110051.pdf</u>



https://www.ijmr.org.in/temp/IndianJMedRes1392195 -397834_110303.pdf



Advisory developed by the following experts & National Task Force for COVID-19

- Dr. Arunaloke Chakrabarti, Professor & Dr. Pankaj Buch, Professor, Deptt. of Head, Department of Medical Microbiology, PGIMER, Chandigarh
- Dr. Atul Patel, Infectious Disease Specialist, Dr. Sejal Mistri, Associate Professor, Ahmedabad
- Dr. Rajeev Soman, Consultant Infectious Disease Physician, Pune
- Dr. Prakash Shastri, Vice Chairman, Critical Professor, Deptt. of Internal Medicine, Pt. Care, Sir Ganga Ram Hospital, New Delhi
- Dr. J P Modi, Medical Superintendent, Dr. K J Upadhay, Head, Deptt. of Internal • Dr. Samiran Panda, Head, Epidemiology Medicine and Multi-disciplinary Clinical Management Group, BJ Medical College & Civil Hospital, Ahmedabad
- Dr. Girish Parmar, Dean, Government Dental College & Hospital, Ahmedabad
- Dr. Janak Khambolja, Professor, Deptt. of
 Dr. Madhuchanda Das, Scientist D, ECD, Internal Medicine, Smt. NHL Municipal Medical College, Ahmedabad
- Dr. Hemang Purohit, Medical Microbiologist, Smt. NHL Municipal Medical College, Ahmedabad
- Dr. R S Trivedi, Medical Superintendent, Pt. Dindayal Upadhyay Medical College, Rajkot

ICWS

DIAN COUNCIL O EDICAL RESEARC



- Pediatrics, Pt. Dindayal Upadhyay Medical College, Rajkot
- Deptt. of ENT, Pt. Dindayal Upadhyay Medical College, Rajkot
- Dr. Deepmala Budhrani, Assistant Dindayal Upadhyay Medical College, Rajkot
- & Communicable Diseases (ECD), ICMR, New Delhi
- Dr. Aparna Mukherjee, Scientist E, Clinical Trial & Health Systems Research Unit, ECD, ICMR, New Delhi
- ICMR, New Delhi
- Dr Tanu Anand, Scientist D, Clinical Trial & Health Systems Research Unit, ECD, ICMR, New Delhi
- Dr Gunjan Kumar, Scientist C, Clinical Trial & Health Systems Research Unit, ECD, ICMR, New Delhi

