

Ruj. Kami : KKM. T.600-8/37/53 (8)

Tarikh : 24 September 2024

## Senarai Edaran

YBhg. Datuk/Dato'/Tuan/Puan,

### **CRITERIA ON THE USAGE OF INTRA-ARTICULAR HYALURONIC ACID (IAHA) INJECTION FOR OSTEOARTHRITIS OF VARIOUS JOINTS.**

Dengan hormatnya perkara diatas dirujuk.

2. Untuk makluman, Bahagian Amalan Perubatan telah menerima banyak aduan daripada pengamal perubatan di fasiliti kesihatan swasta dan juga syarikat syarikat insuran berkenaan kegunaan IAHA untuk pesakit *osteoarthritis* yang melibatkan pelbagai sendi.

3. Susulan itu, Bahagian ini telah bekerjasama dengan *The Malaysian Orthopaedics Association, Malaysian Arthroscopy Society and Malaysian Society of Hip and Knee Surgeons* serta merujuk kepada Cawangan Penilaian Teknologi Kesihatan (MaHTAS), Kementerian Kesihatan Malaysia telah menghasilkan dokumen ini sebagai panduan kepada pengamal pengamal perubatan di fasiliti kesihatan swasta.

4. Sehubungan itu, semua pengamal perubatan di fasiliti kesihatan swasta dinasihatkan untuk mematuhi kriteria yang telah ditetapkan di dalam garis panduan ini yang terpakai mulai Oktober 2024.

Sekian, terima kasih

**"MALAYSIA MADANI"**

**"BERKHIDMAT UNTUK NEGARA"**

Saya yang menjalankan amanah,

(DR. MOHAMED IQBAL BIN HAMZAH)

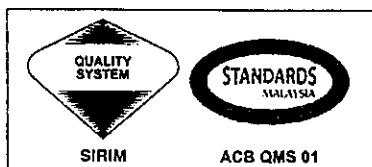
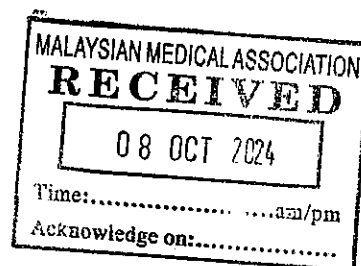
(No. MMC: 33644; NSR: 136304)

Pengarah

Bahagian Amalan Perubatan

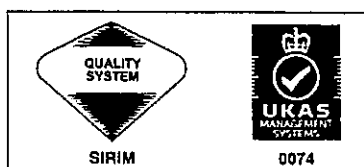
Kementerian Kesihatan Malaysia

Hs/mcofee/sept/2024



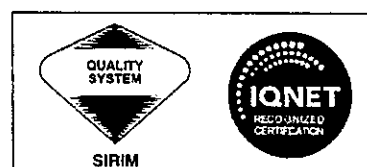
CERTIFIED TO ISO 9001:2015

CERT. NO. QMS 01/007



CERTIFIED TO ISO 9001:2015

CERT. NO. QMS 01/007



CERTIFIED TO ISO 9001:2015

CERT. NO. QMS 01/007

# **CRITERIA ON THE USAGE OF INTRA-ARTICULAR HYALURONIC ACID (IAHA) INJECTION FOR OSTEOARTHRITIS (OA) PATIENTS**

## **1. Introduction:**

Osteoarthritis (OA) is a degenerative condition of joints and is the most common form of arthritis. It frequently affects the hands and weight bearing joints including knee, hip and spine. The severity of OA can range from very mild to very severe. There is no cure for OA and current treatment focuses on relieving symptoms and improving function and to avoid progression of symptoms.

Viscosupplement or Hyaluronic Acid (HA) has gained popularity as a treatment option for non-operative management of patients with OA of the large joints. Research has demonstrated that local biology within the joint is significantly improved with IAHA injections resulting in decrease in pain and better function.

This criteria is provided to help registered medical practitioners (RMPs) to provide more appropriate, safe, effective and sustainable treatment modality for OA patients.

## **2. Objectives:**

- 2.1 To outline the appropriate indications and contraindications for IAHA injection in OA patients.
- 2.2 To ensure proper screening and investigation (e.g: imaging) of OA patients by the treating RMPs before administration of IAHA injection.

## **3. Principles:**

- 3.1 RMPs must have a valid Annual Practicing Certificate (APC).
- 3.2 RMPs must be trained to give IAHA under aseptic technique in a clean environment.
- 3.3 IAHA used must be registered with the Medical Device Authority (MDA) of the Ministry of Health Malaysia.
- 3.4 Written consent must be obtained by the treating RMP before IAHA injection is performed.
- 3.5 RMPs may **only administer a single injection per joint per session** in accordance to the manufacturer's recommendation.

- 3.6 IAHA injection **should not be used** as a routine replacement of synovial fluid during large joint procedures.
- 3.7 Radiofrequency ablation (RFA) and IAHA **should not be performed** together at the same setting.
- 3.8 IAHA **should not be used** as the first-line management for symptomatic osteoarthritis.
- 3.9 IAHA injection **do not benefit** for knee meniscus or ligament injury.
- 3.10 The use of IAHA with sorbitol and mannitol in OA **is not recommended** due to insufficient evidence.
- 3.11 All RMPs must comply with the Code of Professional Conduct of the Malaysian Medical Council (MMC) or the Private Healthcare Facilities and Services Act 1998 (Act 586) or any other relevant legislation.

#### **4. Indications:**

- 4.1 IAHA may be used in the surgical management of patients with mild to moderate glenohumeral osteoarthritis for symptomatic relief. However, the observed benefits are primarily short-term.
- 4.2 IAHA may be administered for patients with knee osteoarthritis classified as Grade I to III (**Kellgren and Lawrence classification**) These injections are intended for short-term (less than 6 months) symptomatic relief and not considered a curative treatment.
- 4.3 Symptomatic adults with Grade I to III OA of knee and shoulder joint affecting functional activities of daily living with clinical and radiological evidence of the disease.
- 4.3 Kellgren and Lawrence classification for grading of knee osteoarthritis is as the following:
  - I. **Grade 0 (none):** define absence of x-ray changes of osteoarthritis
  - II. **Grade 1 (doubtful):** doubtful joint space narrowing and possible osteophytic lipping;
  - III. **Grade 2 (minimal):** definite osteophytes and possible joint space narrowing;

- IV. **Grade 3 (moderate):** moderate multiple osteophytes definite narrowing of joint space and some sclerosis and possible deformity of bone ends; and
  - V. **Grade 4 (severe):** larger osteophytes, marked narrowing of joint space, some sclerosis and possible deformity of bone ends.
- 4.5 Patients with confirmed OA of knee and shoulder joint who have failed non-pharmacologic (physical therapy and lifestyle modifications) or pharmacologic therapies such as conservative treatment including and / or pharmacotherapy (non steroidal anti inflammatory drugs) and analgesics for at least 6 weeks for Kellgren and Lawrence Grade III and at least 12 weeks for Kellgren and Lawrence Grade I and II.
- 4.6 History of previous joint surgery for degenerative joint disease.

## **5. Contraindication:**

- 5.1 Grade IV (severe), large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone ends according to Kellgren and Lawrence system.
- 5.2 Hypersensitivity to HA.
- 5.3 Infections or skin diseases in the vicinity of the injection site or injection into a septic joint.
- 5.4 Joint with open wound.

## **6. Conclusion:**

This criteria is formulated to ensure RMPs to provide, safe, effective and sustainable treatment modality for OA patients. It will also address issues faced by insurance companies and RMPs regarding the usage of IAHA among OA patients.

## **References:**

Aidatul Azura AR, K1 Ismail, Amir Hazman K, Muhammad Ainuddin A and Izzuna MMG. Hyaluronic Injection for Various Joint Disorders. Technology Review. Ministry

of Health Malaysia. Malaysian Health Technology Assessment Section (MaHTAS);  
2023.218 p.Report No: 0014/2023. eISSN.

## **Distribution List:**

Dr. T. Mahadevan  
Chief Executive Officer (CEO)  
Association of Private Hospitals of Malaysia (APHM)  
A-17-01, Menara UOA Bangsar  
No.5, Jalan Bangsar Utama 1  
**59000 KUALA LUMPUR**

The President  
Life Assurance Association Malaysia (LIAM)  
No.4, Lorong Medan Tuanku 1  
Medan Tuanku  
**50300 KUALA LUMPUR**

The President  
General Insurance Association of Malaysia  
3rd Floor, Wisma PIAM  
150, Jalan Tun Sambanthan  
**50470 KUALA LUMPUR**

The Chairman  
Malaysia Takaful Association  
Menara Takaful Malaysia  
21<sup>st</sup> Floor, Main Block  
No.4, Jalan Sultan Sulaiman  
**50000 KUALA LUMPUR**



The President  
Malaysian Medical Association  
4th floor, 124 Jalan Pahang  
Titiwangsa Sentral  
**53000 KUALA LUMPUR**

The President  
Malaysian Orthopaedics Association  
19, Jalan Folly Barat  
Off Jalan Ledang  
**50480 KUALA LUMPUR**  
The President

Malaysian Society of Hip and Knee Surgeons  
National Orthopaedic Centre of Excellence in Research and Learning  
(NOCERAL) Department of Orthopaedic Surgery  
Faculty of Medicine, University of Malaya  
**50603 KUALA LUMPUR**

The President  
Malaysian Arthroscopic Society  
C/O Le Events Sdn. Bhd  
13-1, 1<sup>st</sup> floor, Jalan Puteri 1/4  
Bandar Puteri Puchong  
**47100 SELANGOR**