

August, 2017

## Department of Pharmaceuticals National Pharmaceuticals Pricing Authority, Drugs (Prices Control) Order dated 16th, August 2017

The Ministry of Chemicals and Fertilizers Department of Pharmaceuticals National Pharmaceuticals Pricing Authority, vide Drugs (Prices Control) Order (“DPCO”) no. F.No 8(48)/2017/DP/NPPA/Div II, dated 16<sup>th</sup> August 2017 fixed and notified the ceiling prices of orthopedic knee implants for knee replacement system. The ceiling prices fixed are to be maintained for a period of one year from the date of the said notification, unless revised by another gazette notification.

The revised ceiling prices of orthopedic knee implants for knee replacement system, along with the explanatory notes, as specified are summarised below:

Sl. No.	Orthopedic knee Implant system	Component	Feature/Material of the knee implant	Units (In Number)	Ceiling Price (In Rs.)
1.	2.	3.	4.	5.	6.
1)	Primary knee replacement system	Femoral component by whatsoever name/specification	Titanium alloy (all variants) coated	1	38,740
2)	Primary knee replacement system	Femoral component by whatsoever name/specification	Oxidized zirconium (OxZr) alloy (all variants)	1	38,740
3)	Primary knee replacement system	Femoral component by whatsoever name/specification	Hi-flex	1	25,860
4)	Primary knee replacement system	Femoral component by whatsoever name/specification	Cobalt chromium (CoCr) alloy (all variants)& other than at serial no 1,2 and 3	1	24,090
5)	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Titanium alloy (& it's all variants) coated	1	24,280
6)	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Oxidized Zirconium (OxZr) Alloy	1	24,280

7)	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Cobalt chromium (CoCr) alloy & other than at Serial no 5 and 6	1	16,990
8)	Primary knee replacement system	Articulating surface or Insert by whatsoever name/specification	Any Material	1	9,550
9)	Primary knee replacement system	Patella by whatsoever name/specification	Any Material	1	4,090
10)	Primary knee replacement system	Component having Tibial tray and Insert combined as single unit by whatsoever name/specification	Polyethylene or cross-linked polyethylene or highly cross-linked polyethylene or any other material	1	12,960
11)	Primary knee replacement system	Component having Tibial tray and Insert combined as single unit by whatsoever name/specification	Tibial: Metallic Insert: Polyethylene or Cross-linked polyethylene or highly cross-linked Polyethylene or any other material	1	26,546
	<b>REVISION</b>				
12)	Revision Knee Replacement system	Femoral Component by whatsoever name/specification	Any material	1	62,770
13)	Revision Knee Replacement system	Femoral Component by whatsoever name/specification	Any material	1	31,220
14)	Revision Knee Replacement system	Femoral Component by whatsoever name/specification	Any material	1	15,870
15)	Revision Knee Replacement system	Femoral Component by whatsoever name/specification	Any material	1	4,090

**Note:**

- All manufacturers are required to comply and implement the ceiling prices mentioned in the Pricing Order.
- For Special orthopedic knee implants for cancer/tumor etc will follow the prices of revision surgery and if the import prices are higher, manufacturers may add a total margin of maximum 30 percent over the import price of the first batch and apply to NPPA for a retail price notification at the earliest.

- All manufacturers of knee Implants, selling branded or non-branded or both versions of implants at prices higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the price downward not exceeding the ceiling price.
- All manufacturers/marketers of knee implants having MRP lower than the ceiling price shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.
- The ceiling price for a pack of implant shall be arrived at by the concerned manufacturer/importer in accordance with the ceiling price specified as per the provisions under DPCO, 2013.
- The Ceiling prices fixed by the Government are inclusive of all components and consumables, which are used in the knee implant procedure and remain in the body of the patient.
- The manufacturers under Paragraph 24 of DPCO, 2013 shall issue price list in Form– V as prescribed in Schedule II of the DPCO, 2013 to the NPPA through Integrated Pharmaceutical Database Management System (IPDMS) and submit a copy to all State Drug Controllers and all its distributors/dealers/orthopedic healthcare institutions.
- Every distributor, dealer and institution shall display price list and the supplementary price list, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.
- Wherever institutions such as hospitals/nursing homes/clinics performing orthopedic surgical procedures using knee implants are billing directly to the patients, they shall be required to comply with the ceiling prices notified e and follow the applicable provisions of the DPCO, 2013.
- No healthcare institutions such as hospitals/nursing-homes/clinics performing orthopedic surgical procedures using knee implants shall solicit any patient to purchase knee implants from it, in case, the patient is interested in procuring such implant from any other third-party sources.
- Institutions such as hospitals/nursing homes/clinics utilizing knee implants shall specifically and separately mention the cost of the knee implant component-wise along with its brand name, name of the manufacturer/importer/batch no./specifications and other details, if any, in their estimate/performa invoice/final-billing, etc. to the patients or their representatives.
- Any manufacturer or institution or person not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.
- Where, the manufacturer supply/sell knee implant directly to the orthopedic healthcare institutions, without involvement of any distributor, then the maximum trade margin for hospitals/nursing homes/clinics shall be restricted at 16 percent.

Please feel free to write to us should you like additional information and/or any clarifications on the said Order or for that matter any other aspect of Indian law.

---

*Disclaimer*

*The contents of this document should not be construed as legal opinion.*