कर्मचारी राज्य बीमा निगम
(श्रम एवं रोजगार मंत्रालय, भारत सरकार)
EMPLOYEES' STATE INSURANCE CORPORATION
(Ministry of Labour & Employment, Govt. of India)

मुख्यालय
Headquarters'
पंचदीप भवन सी॰आई॰जी रोड , नई दिल्ली-110002
PANCHDEEP BHAWAN, C.I.G. MARG, NEW DELHI-110 002
Phone: 011-23604700 Email : dir-gen@esic.nic.in
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File No. U-16012/86/2025-SST **Date: 15-04-2026**

To

Director (Medical), Delhi / D(M)N
Dean- All ESIC PGIMSRs, Medical & Dental Colleges

Medical Superintendents – All ESIC/ESIS Hospitals
Regional Directors, RO/SRO-In charge

Subject: Adoption and implementation of Standard Operating Procedure (SOP) for High-Cost Treatment (HCT) cases across all ESIC Institutions.

Sir/Madam,

Enclosed herewith is a copy of the **Standard Operating Procedure (SOP) for High-Cost Treatment (HCT)** for adoption and compliance by all ESIC & ESIS Hospitals, Medical Colleges, Regional Offices, and other concerned field units.

The SOP has been formulated to streamline the processing, scrutiny, and approval mechanism of High-Cost Treatment (HCT) cases, particularly those involving expenditure exceeding ₹10 lakh per beneficiary per financial year, and to ensure uniformity, transparency, and timely decision-making across all locations.

All concerned are requested to ensure **implementation** of the SOP with immediate effect along with adherence to the prescribed guidelines.

This issues with the approval of Competent Authority

Encl.: SOP for High-Cost Treatment (HCT)

Yours faithfully,

Digitally signed by
Bijoy Chandra Deka
Date: 15-04-2026
16:32:39

(B.C. Deka)
Deputy Medical Commissioner

मानक संचालक प्रक्रिया

SOP for HCT

कर्मचारी राज्य बीमा निगम

Employees' State Insurance Corporation

ESIC Operational Manual 2026 for High Cost Treatment

ई.एस.आई.सी उच्च लागत उपचार हेतु प्रचालन नियम-पुस्तक 2026

EMPLOYEES' STATE INSURANCE CORPORATION

कर्मचारी राज्य बीमा निगम

Panchdeep Bhawan, C.I.G, New Delhi-110002

पंचदीप भवन, सी.आई.जी, नई दिल्ली-110002

वेबसाइट/Website: www.esic.gov.in

PREFACE

The Employees' State Insurance Corporation (ESIC), functioning under the administrative control of the Ministry of Labour & Employment, Government of India, is committed to provide comprehensive medical care and social security benefits to insured persons and their dependents under the ESI Scheme.

ESIC ensures access to a wide spectrum of healthcare services, including super-specialty care and life-saving treatments, thereby safeguarding the health and well-being of its beneficiaries. In view of the increasing complexity and cost of advanced medical care, a structured and uniform mechanism for managing High-Cost Treatment (HCT) cases has become essential.

HCT cases, defined as those exceeding ₹10 lakh per beneficiary per financial year, typically involve critical conditions requiring high-cost drugs, procedures, or long-term therapies such as oncology care, organ transplantation, and enzyme replacement therapy. These cases necessitate a judicious balance between timely clinical intervention, financial prudence, and regulatory compliance.

This Standard Operating Procedure (SOP) establishes a standardized framework for the evaluation, approval, and monitoring of HCT cases across ESIC institutions. It is intended to ensure uniformity in decision-making, reduce procedural delays, and strengthen transparency, accountability, and audit compliance.

The SOP prescribes a committee-based, time-bound approval mechanism supported by clinical verification, financial scrutiny, and adherence to applicable guidelines, including CGHS rates and ESIC rate contracts. It also mandates proper documentation, standardized e-File processing, and regular reporting to Headquarters.

While ensuring strict financial governance, the SOP prioritizes patient welfare by facilitating timely access to essential treatment. It is to be implemented in conjunction with all extant rules, circulars, and policy directions issued by the competent authority from time to time.

INDEX

Standard Operating Procedure for High-Cost Treatment

Background:

High-Cost Treatment are cases where the expenditure exceeds ₹10 lakh (including GST/Taxes, where applicable) per beneficiary per financial year for all such packages, treatments, or drugs which are not covered under the CGHS/ESIC Central Rate Contract. These cases are predominantly Life-Saving emergency and critical in nature, warranting an expedited approval mechanism.

Since these cases have significantly high financial implications, such cases require strict adherence to prescribed guidelines, comprehensive justification, and due diligence to address audit, vigilance, and potential misuse concerns, thereby necessitating approval at the highest level. However, procedural delays in approval often result in disruption of patient treatment, legal implications, and public grievances.

In order to streamline the processing of High-Cost Treatment cases and to minimize delays in approvals of cases received from various field locations at the Headquarters level, the above Committee has been constituted by the competent authority.

1. **High-Cost Treatment (HCT) Cases** are redefined as cases where the total expenditure exceeds ₹10 lakh (inclusive of GST/Taxes, wherever applicable) per beneficiary per financial year for current spell of sickness or active treatment of chronic disease, falling under the following categories:

a. **Planned, non-emergency procedures** not covered under CGHS Package Rates — *requiring approval of the ESIC Headquarters High-Cost Treatment (HCT) Committee*.

b. **Medical treatment of beneficiary involving drugs** not listed under DG ESIC Rate Contract— requiring approval of the ESIC Headquarters High-Cost Treatment (HCT) Committee.

c. **All other cases**, including treatment involving drugs covered under DG ESIC Rate Contract, procedures covered under CGHS Package Rates, and emergency procedures — *to be dealt with at the Location Level as per existing delegated powers*.

2. **Reference to Point 1(c):** The cost of chemotherapy/immunotherapy drugs (e.g., in cases of cancer, hemophilia, etc.) which are available under DG ESIC Rate Contract (DGESI-RC) be also counted towards the ceiling of expenditure of Rs. 10 Lakhs (including GST/Tax as applicable) per beneficiary per financial year for the complete spell of treatment of the disease. This is necessitated by the fact that drugs covered under the Rate Contract many a times, fall outside the Rate Contract upon expiry of the RC, thereby becoming non-RC items. To ensure uniformity and consistency in policy implementation, such cases be approved at the local level by the Local High-Cost Treatment Committee (LHCTC). The composition of the Local High-Cost Treatment Committee (LHCTC) shall be as under: (ERT, Transplant, High Cost Drugs)

a. MS in Medical Colleges Hospitals & DMS/AMS in other Hospitals.
b. Representative of SST Cell/In charge
c. Specialist of the concerned Department/Parent Broad Speciality Dept.
d. Specialist of the concerned department/Parent Broad Speciality Dept. from other ESIC Hospital. (video Conference & Digital mode)
e. Head of Finance division.

All such records shall be maintained at the local level, and a monthly consolidated report shall be forwarded to ESIC Headquarters (SST Division). These records shall be subject to audit.

3. **The management of referred ICU cases and other emergency cases:** The expenditure incurred thereon, shall be treated as covered under CGHS Rates and shall be decided at the local level by a duly constituted committee and such committee members not to be fixed and should be constituted based on the cases and availability of Doctors. Dean/MS shall constitute such committee based on the type of cases and requirement of experts. RDs to request MSs/Deans for such Doctors and if due to some reason physical verification is not possible then they can take the help of technology like video consultation etc. For ICU cases, MS/Dean while constituting committee shall preferably include one Doctor from Anesthesia/ICU Department, in this case RD shall request nearest ESIC/ESIS Hospitals/Medical Colleges for examination by LHCTC.

4. All cases involving pre-existing diseases, such as malignancies, chronic renal failure, diseases requiring enzyme replacement therapy (ERT), and transplant cases, falling under Super Specialty Treatment (SST) and entailing high-cost treatment, shall be subjected to thorough verification of the Insured Person (IP) in accordance with the prescribed checklist including actual working status of the IP with the employer concerned.

5. In cases of organ transplant and bone marrow transplant, payment shall be restricted to the rates applicable for related donors only. Further, in cases of organ transplant associated with malignancy, the transplant shall be restricted to the organ affected by the primary malignancy.

6. Cases where such treatment is proposed to be undertaken in Government/Government-undertaking/Autonomous Institutes, the cost estimates shall be obtained from the concerned institute. However, as a matter of policy, treatment in Government institutions shall be preferred wherever feasible an. In case patient seeks treatment in Private Hospital, then the ceiling rate be as per CGHS/AIIMS/Govt Center of Excellence. Existing-"As per referral policy, first preference shall be to refer the patient to a government hospital within their state or neighboring states with BMT facilities. If not available, patient be referred to empanelled tie-up center for BMT within the State or neighboring states having BMT empanelment. It is imperative to prioritize empanelled hospitals whenever possible, reserving consideration of non-empanelled facilities only as a last resort. Any decision to recommend a non-empanelled hospital must be accompanied by thorough justification when forwarding the case to the Headquarters office for review."

7. In all cases of Enzyme Replacement Therapy (ERT) (such as Hunter's syndrome, Gaucher's disease Type III, etc.), Prior approval of ESIC Headquarters shall be obtained at the outset of treatment, as these cases invariably involve very high and recurring expenditure, often running into crores. The recommendations of the Local High-Cost Treatment Committee (LHCTC), with the approval of the competent authority, shall be forwarded to the ESIC Headquarters(SST Division) before the initiation of the treatment.

Further, in ERT cases, only prescriptions issued by Centers of Excellence/AIIMS/PGI, by senior-level specialists/faculty, shall be considered, considering the highly specialized nature of the treatment. During procurement of Proprietary drugs, Locations to ensure that no alternative/biosimilar are available in the market, at the time of each such procurement. All the guidelines for ESIC Rare Disease Manual should be followed.

All High-Cost Treatment (HCT) cases pertaining to State ESI Hospitals /State ESI Cases should be forwarded to the ESIC Hospital/ESIC Medical College of the concerned State/Region/Zone through RD office of the State/Zone, based on availability, for detailed examination and onward submission to ESIC Headquarters. LHCTC of ESIC Hospitals/Medical Colleges will examine all such cases and if recommended for treatment, the same should be forwarded to ESIC Hqrs(SST Division). In States/Regions/UTs where ESIC Hospital or ESIC Medical Colleges are NOT available the case needs ESIC Hqrs approval for High-Cost Treatment (HCT) and Enzyme Replacement Therapy (ERT), shall be forwarded to Medical Commissioner (Zonal) duly attaching all the required documents through e File. MC(Z), shall take the opinion of LHCTC of any ESIC Institutes in the Zone as the case may be & forwarded to ESIC Hqrs.

9. **Checklist for Documents:**
    1. Complete Case e-File to be sent to MC/DMC (SST), HQ
    2. Separate e-File for each High Cost Treatment to be created.
    3. Forwarding letter with due recommendation of Competent Authority(MS/Dean)
    4. **Document Submission Guidelines:**
        a. All approvals shall be initiated through the e-File system. Upon receipt of the e-file at ESIC Headquarters, an extract of the file shall be taken and the original e-file shall be returned to the concerned location. A Table of Contents (TOC) shall be used for proper indexing in chronological order, comprising, inter alia: High-Cost Treatment (HCT) Proforma, Geneticist's report, prescriptions, target-parameter reports, and certification by the Geneticist, as per the prescribed checklist.

b. All documents shall be uploaded and arranged strictly in chronological order, as specified in the prescribed proforma.

c. Only recent and relevant documents, valid for the period for which approval is sought, shall be submitted. Prescriptions shall not be older than three months from the date of submission.

d. A separate e-file shall be maintained for each patient to facilitate ease of examination, approval, and sanction of expenditure. Accordingly, locations shall create individual e-files for each beneficiary, and the same practice shall be followed at ESIC Headquarters.

e. All case papers shall be placed under the Table of Contents (Correspondence section) of the e-file, and not as standalone attachments. Relevant documents shall be hyperlinked in the noting portion in the prescribed proforma (Annexure-A).

f. At the first instance, the location shall procure/execute expenditure up to ₹10 lakh inclusive of GST/Tax for the concerned beneficiary within its delegated powers (DoP) for the relevant financial year and forward the case thereafter in accordance with the prescribed policy, **except in Enzyme Replacement Therapy (ERT) cases,** where prior Headquarters approval is mandatory.

5. Duly Filled & Signed HCT Proforma: with all relevant document

6. **Verification Report**

   a. Submission of Genuinity Verification report: Verification of the Insured Person (IP) and family identity documents, as well as IP employment particulars, shall be undertaken through scrutiny of original attendance and wage registers, salary bank account statements, Aadhaar Card, PAN Card, and other relevant records, to confirm that the IP is genuinely employed and that wages have been paid in accordance with the contributions filed. The verification report shall be countersigned by the Regional Director of the concerned State/Region.

b. In all cases involving pre-existing diseases, verification of the previous employment history of the IP shall also be carried out, and the report there of shall be duly attached.
c. A Super Specialty Treatment (SST) eligibility certificate, duly signed by the Regional Director, shall be submitted along with the case file.
d. All IP verification reports shall be not older than six months from the date of submission and shall be signed and endorsed by the Regional Director of the respective State/Region.

7. **e-Pehchan Card:**
    a. Include Pehchan cards with recent photographs of all listed dependents duly signed.
    b. Countersigned by ESIC Branch Office.
    c. Aadhaar linking
8. **SST Eligibility:** In respect of all HCT cases for SST eligibility, the prevailing ESIC policy/guidelines, including amendments issued from time to time, shall be applicable.
9. **Valid Prescriptions and Specialist Opinions:** In ERT cases opinion of a Centre of Excellence (CoE) shall be mandatory, preferably from Government/Government Undertaking institutions, AIIMS, PGI, Tata Institutes, or other recognized Centres of Excellence. In cases where no such Centre of Excellence is available within the concerned State/Region, the opinion to be obtained from the nearest available or any other recognized Centre of Excellence outside the State/Region. In such cases, TA/DA, as admissible under the extant rules and guidelines, be granted. In other HCT cases, second opinion from Government/Government Undertaking institutions, AIIMS, PGI, Tata Institutes, or other recognized Centres is mandatory.
10. **Rate Quotations:**
    a. Should be valid for an extended period or at least one year from the date it is issued.
    b. Shall include fall clause and proprietary certificate, as applicable.
11. **Detailed Case Summary/ History:**

a. For new/fresh cases, include comprehensive clinical history along with Card History (from UTI-ITSL module)

10. **Referral Letter**:
    a. A copy of the latest referral letter, clearly indicating the diagnosis, proposed procedure, and investigations, shall be attached with the case file.
    b. For all approvals, two recent full-size photographs of the beneficiary shall be submitted—one to be affixed to the High-Cost Treatment (HCT) Proforma and one to the referral letter. The photographs shall be duly verified and attested by the Medical Superintendent/Dean, as well as the treating consultant, along with their signatures, as specified in the HCT Proforma. This is intended to facilitate assessment of the beneficiary's general well-being, including parameters such as height and weight. Upon incorporation of the relevant provision in the P1 form, real-time captured photographs shall be uploaded accordingly.

11. **Location should examine as per below mentioned points, before sending/approving for consideration at Hqrs level.**
    a. Availability of any alternative conventional device/treatment for the same indication.
    b. Expert opinion from All India Institute of Medical Sciences / Centre of Excellence, wherever required.
    c. Availability of peer-reviewed outcomes/clinical experience, preferably in the Indian population.
    d. Whether the device/procedure is experimental or under trial.
    e. Whether requisite statutory approval from Indian regulatory authorities for use in India is available.
    f. All the above should accompany relevant documents.

12. **Guidelines for Unlisted High-Cost Devices**
    a. Considering that ESIC currently does not have specific guidelines regarding very high-cost devices/unlisted implants, the following mechanism was agreed upon:

b. Cases involving unlisted implants costing up to ₹10 lakh shall be dealt at the local level through a duly constituted committee, in accordance with the provisions of the Referral Policy, 2023.

c. Non-emergency/planned cases requiring unlisted implants costing above ₹10 lakh shall be referred to Headquarters (HQ) for necessary approval.

Location should examine as per below mentioned points, before sending/approving for consideration at Headquarter level.

- Availability of any alternative conventional device/treatment for the same indication.
- Expert opinion from All India Institute of Medical Sciences / Centre of Excellence, wherever required.
- Availability of peer-reviewed outcomes/clinical experience, preferably in the Indian population.
- Whether the device/procedure is experimental or under trial.
- Whether requisite statutory approval from Indian regulatory authorities for use in India is available.
- All the above should accompany relevant documents.

13. **Other High-Cost Treatment Guidelines:**

a. In all recurring cases, the annual expenditure shall be clearly indicated and verified from the Card History available on the UTIITSL/TMS (NHA) platform, wherein all patient-wise expenditures are recorded. Where any other approved system/process has been utilized in addition to UTIITSL, the expenditure incurred through such sources shall also be taken into account while calculating the annual expenditure. A copy of the Card History shall be enclosed with the case file, as per the prescribed checklist.

b. In respect of drugs and procedures, any case where the total expenditure exceeds ₹10 lakh (inclusive of GST/Taxes, as applicable) shall be treated as a High-Cost Treatment case, irrespective of whether the drugs are Rate Contract (RC) or Non-RC, and whether the procedures/treatments are covered or not covered under CGHS Package Rates.

c. However, cases involving RC drugs, CGHS-covered procedures, and emergency treatments shall be examined and approved at the local level by the Local High-Cost

Treatment Committee (LHCT) in a manner analogous to the scrutiny undertaken by the HCT Committee at ESIC Headquarters.

d. Planned, non-emergency procedures not covered under CGHS Package Rates and drugs not included in the DG ESIC Rate Contract (DGRC) shall, however, require approval of the ESIC Headquarters High-Cost Treatment (HCT) Committee.
e. All requests shall reach ESIC Headquarters at least 4–6 weeks prior to the expiry of the previously approved period or sanctioned dosage. This is essential in view of the time involved in the approval process, procurement, and delivery of medicines, so as to ensure uninterrupted continuity of treatment.
f. All locations shall maintain complete and proper records of all High-Cost Treatment (HCT) cases in both digital and hard copy form, with full details as prescribed in the HCT Proforma.
g. Each location shall obtain from the treating consultant the complete expected treatment schedule, including detailed cycles/course of therapy and the dosage of medications, duly calculated in terms of the patient's body weight and/or body surface area, as applicable.
h. While calculating the dosage of medicines naked body weight of the patient to be considered as all such treatments are weight/body surface area dependent.

14. **Specific Case Requirements:**

A. **For all HCT Cases requiring ESIC Headquarter Approval:**

a. In cases related to malignancy, a Tumor Board opinion shall be mandatory. For cases involving Non–DG ESIC Rate Contract (RC) drugs and planned, non-CGHS procedures, the recommendation of the Local High-Cost Treatment (HCT) Committee shall also be required.
b. All relevant clinical, laboratory, imaging, and investigation reports shall be enclosed with the case file.
c. The use of under-trial / experimental drugs is strictly prohibited.
d. Empty vials of administered medicines shall be preserved in good condition by the treating hospital and/or the patient, ensuring that details such as batch number, manufacturing/expiry details (MRD), etc., remain legible. These empty vials shall

be submitted to the concerned ESIC location prior to release of subsequent doses. This measure shall also serve as verification of regular utilization of medicines, and utilization certificates shall be issued on this basis only.

e. For all cases involving Non–DG ESIC RC drugs, the prescribed 18-point proforma shall be mandatorily enclosed along with the HCT Proforma, duly signed and endorsed by the competent authority.

B. **For Enzyme Replacement Therapy (ERT) Cases:**

a. A Local Committee shall be constituted comprising the following members: 1. Medical Superintendent (MS), 2. Head of the concerned Department of the ESIC Hospital, 3. Head of the concerned Department of AIIMS/Government Medical College/other ESIC Medical College. The committee's recommendation, along with the latest prescription and opinion of the Centre of Excellence (CoE), must be submitted every time the case is forwarded, for each approval or submission, as applicable.

b. All Enzyme Replacement Therapy (ERT) cases shall be examined in the light of the National Policy for Rare Diseases (NPRD), 2021. Headquarters Office, vide letter dated 26.05.2023, has issued directions regarding parental counseling and preventive measures for rare diseases. Accordingly, locations shall ensure that parental counseling is conducted in the instant cases in accordance with the prescribed guidelines.

c. Achievement of target parameters for the specific disease, after initiation of treatment, shall be assessed based on disease-specific standards (e.g., BOX-2 criteria, wherever applicable) and shall be certified by the treating specialist. The same shall be clearly recorded in the prescribed Proforma.

d. A comprehensive mental and developmental assessment (including IQ and DQ), along with evaluation of any associated co-morbidities and hormonal status, shall be submitted as part of the case documentation.

15. **Essential Documents for Subsequent Approval of High-Cost Treatment (HCT) Cases:**

Following documents are mandatory while seeking subsequent approval:

a. Genuineness Verification Report of the Insured Person (IP) and family.
b. Utilization Certificate for previously sanctioned medicines/treatment.
c. Latest Progress Report, including mental and developmental assessment (IQ & DQ).
d. Specialist Opinion, which must not be older than three months.
e. Valid Quotations (with valid date, price, and fall clause) in accordance with GFR provisions, along with proprietary certificate, if applicable.
f. Recent Laboratory and Imaging Reports relevant to the treatment.
g. Latest Prescription with dosages (calculated per kg naked body weight or body surface area), issued by the specialist at the Centre of Excellence / AIIMS / PGI, mandatory for all ERT cases.

16. **Bone Marrow Transplant (BMT) Cases:**

a. First priority shall be given to ESIC Hospital, Sanat Nagar / ESIC Hospital, Faridabad, or any other ESIC institutes where in-house facilities for the required treatment is available. Initial Consultations be done through Video/Tele consultations also.
b. Clause 25.1 of the Operational Manual (2023) shall be followed: *"In the case of organ transplant and bone marrow transplant, payment shall be limited to the rates applicable for the related donor. Additionally, for organ transplants involving malignancies, only the transplant of the organ with the primary malignancy will be allowed. This measure aims to prevent potential misuse of the facility."* All other relevant operational and policy provisions shall also be adhered to.
c. Payments shall be restricted to rates applicable for related donors only.
d. All applicable policies, as amended from time to time, shall be followed, and the official website shall be checked regularly for updates.
e. Donor cell/organ costs must be excluded from quotations, as these are not reimbursable by ESIC.
f. As per the Referral Policy, preference shall be given to government hospitals within the patient's State or neighbouring States with BMT facilities. If not available, the patient be referred to empanelled tie-up centres for BMT within the State or

neighbouring States. Empanelled hospitals must be prioritized, and non-empanelled facilities considered only as a last resort. Any recommendation to a non-empanelled hospital must include thorough justification when forwarding the case to Headquarters.

g. Annexures A to H to be countersigned by **MS/Dean/RD** as the case may be.

17. **Others Digitalization & Extension of Stay Cases:**

a. **Development of Digital Platform**

- Digital platform to monitor High-Cost Treatment cases in collaboration with ICT will be developed.

b. **Alert Mechanism for High Expenditure Cases specially ICU related cases.**

- Alerts shall be triggered through SMS/WhatsApp/App for cases exceeding ₹5 lakh
- Subsequent alerts shall be generated for every ₹2.5 lakh thereon.
- Alerts shall be visible at MS/RD levels
- This will facilitate timely verification by MS/RD through physical inspection or video-based verification as the case may be.

c. **Concurrent Audit by TPA**

- A pilot study will be conducted to assess feasibility and effectiveness before wider implementation.

18. **Reconstitution of High-Cost Committee:**

1. **Chairperson of HCT Committee-**Medical Commissioner (ME)
2. **BMT Cases-** Dr. Kanwaljeet Kaur &Dr. Bijita Dutta
3. **ERT Cases-**Dr. Kanwaljeet Kaur &Dr. Anand Kumar, Specialist (Medicine), ESICH Rohini
4. **Cancer Cases-**Dr. Paramesh S. &Dr. B. Arun Kumar Barad
5. **Nephrology Cases (acute & chronic kidney problems)-** Dr. SahilArora & Dr. Deepthi Ayanavelli, Nephrologist
6. **Gastrointestinal Cases (stomach cancer and digestive disorders)-**Dr. Prabhat Narain and Dr. Anand Kumar Specialist, (Medicine), ESICH Rohini
7. **Neurological Cases-**Dr. Arifa Rahman, Neurologist

8. **Other Linked Doctors of Medicine Department-** Dr. Rajiv Kumar Bandaru, General Medicine and Dr. Chennkeshavulu Dara, General Medicine and Dr. Abhilash VB, Gastroenterologist (ESIC Hospital Asramam)

Note: High Cost Committee can adopt any other specialist or super speciality as per requirement.

Annexure- A

COMMON HCT PROFORMA FOR ALL CASES:

S. No.	Information Required	Reply	Corresponding Page No. in TOC (Where document attached)
1.	Recent Full size Clear & good quality Photograph of the Patient should be attached and to be countersigned by treating Consultant & MS/Dean after Physical verification	Space for Photo	
2.	Insurance Number		
3.	Aadhaar Number		
4.	PAN number parents & Patient		
5.	Name of the Patient & Relation with the IP		
6.	Name of the Insured Person		
7.	Date of Registration in ESIC		
8.	Current working status of IP (YES/NO)		
9.	SST Eligibility of IP/Family Members, as the case may be (As on date)		
10.	SST Eligibility of IP/Family Members, as the case may be (On the start of treatment)		
11.	Any change in Insurance Number (If yes, reason thereof) after the treatment.		
12.	Age/DOB of the Patient		
13.	Diagnosis and Date of Diagnosis of the disease		
14.	Institute where Diagnosis was made.		
15.	High-Cost Medicine prescribed, dose per kg/Sqm of body surface area and frequency of Administration		
16.	Naked Weight of the patient at the time prescribed the dose. To be verified by ESIC		
17.	Name of the Treating Genetist& Contact No.		
18.	Name of treating Institute & Address		
19.	Justification for use of the drug for the Diagnosis -From Genetist.		
20.	Drug/Drugs for which Permission is needed is not under trial and has been Approved by FDA		

21.	Is there any scheme running for the drug under question. Like some dosage free with some purchased dose.		
22.	If any internationally accepted guidelines for such treatment- Reference is needed from Genetist		
23.	Date of Start of Initial Treatment (Other institute, specify if any)		
24.	Date of start of treatment in ESIC		
25.	Total expenditure incurred in current FY date (in ₹)		
26.	Cumulative expenditure incurred till date (Copy of Card History from UTI-ITSL Portal to be attached, if applicable)		
27.	Average annual expenditure (in ESIC) (in ₹) [(Total expenditure/month) *12]		
28.	Sanctioned amount and period for which last approved by ESIC Hqrs.		
29.	Period for which the current approval is required (From & to date)		
30.	Whether patient was under continuous follow up (documents)		
31.	Any break in treatment (From & to date) & Justification of gap in current treatment, if any		
32.	Clinical condition of the patient during break period		
33.	Any increase or decrease of dose (Justification for the same)		
34.	Second opinion from AIIMS/Govt. Hospital/ Autonomous bodies of adjacent Regions (YES/NO)		
35.	Whether the drugs/treatment of cases where use of High Cost Drugsis required (Cancer/Hemophilia etc.) listed under DG-ESIC RC/CGHS Package. If yes then mention CGHS Code/ RC no.		
36.	Whether permission for treatment going above Rs. 10 Lakhs is being sought for the first time for the said beneficiary in the current fiscal year. If No, then attach details of utilization Certificate of the sanctioned amount.		

37.	Please attach the documents in respect of recommendation of Specialist of ESIC Hospital, (in admission cases please attach the latest visit report of ESIC Specialist along with his/her recommendation/comments)		
38.	Whether empanelled hospital from which treatment is to be sought is NABH/non-NABH		
39.	Required Estimate (Itemized Breakup) of treatment		
40.	Report of the Local HCT Committee		
41.	Valid Rate Quotation, proprietary certificate and Fall clause attached in case of Non DGESIC drugs.		
42.	Detailed Case Summary in chronological order		

Signature and Stamp of MS/Dean/RD

Annexure - B

Non-DG-ESIC Drugs PROFORMA:

Sl. No.	Questions
1.	Justification for use of non-Rate Contract drug.
2.	Any alternate molecule available in RC & whether it has been used.
3.	Whether this molecule/drug is under trial/experiment if yes a copy of outcome of trials submitted to FDA & DGCI?
4.	Any other company/generic brand available.
5.	Guidelines to use this drug.
6.	Side effects/adverse reactions of this drug.
7.	Whether the same have been communicated to the patient.
8.	Is the patient willing to use this drug on him?
9.	How is the use of this drug beneficial to this patient?
10.	Whether a second opinion regarding use of this drug has been taken from a Government Hospital/Medical College. If yes please enclose details.
11.	What is the percentage benefit/improvement expected by the use of this drug?
12.	What will be the duration of the treatment and expected cost details?
13.	Please provide details & documents of the study showing its beneficial effect.
14.	How many supply order/purchase orders have been placed by the vendor to Govt./PSU for this drug during last 1 year? Copy of last 2 supply orders.
15.	Copy of successful completion of last 2 supply orders.
16.	Copy of FDA & DCGI approval.
17.	Examination and approval from tumour board (in case of medical college/nearby Govt. Hospital/Medical College)
18.	Consent/undertaking of the patient for using the drug.

Signature and Stamp of MS/Dean/RD

Annexure - C

Oncology/Malignant Cases:

S. No.	Information required	Remarks
1.	Complete diagnosis	
2.	Cancer profile:	
	a. Site of cancer	
	b. Type of cancer	
	c. Stage of cancer	
3.	Intent of treatment (Curative/ palliative)	
4.	Diagnostic details-	
	a. Biopsy/ IHC	
	b. Tumor markers	
	c. Molecular studies/ NGS/ targeted mutation studies	
5.	Latest imaging	
6.	Previous treatment:	
	a. Surgery	
	b. Radiotherapy	
	c. Systemic therapy (chemotherapy, immunotherapy, hormone therapy, Targeted therapy) with no. of cycles	
7.	Tumor board opinion- inhouse/ External	
8.	Current proposed plan of treatment- Drug, Duration, Evidence, Cost	
9.	Chemo chart with no. of cycles & doses countersigned by MS	

Signature and Stamp of Specialist **Signature and Stamp of MS/RD/Dean**

Annexure - D

Transplant Cases:

S. No.	Information Required	Reply	Corresponding Page No. in TOC (Where document attached)
1.	For all Transplant cases, In house (ESIC MCH Sanath Nagar & ESIC MCH Faridabad) feasibility recommendation email/letter attached		
2.	Whether the said procedure available under AIIMS/Govt. Hospital/ Autonomous bodies of adjacent Regions (YES/NO) a. If YES, mention the package rate of said procedure (attach documents) with the Name of Hospital and estimated cost with documents. b. If NO, attach estimates preferable from three empanelled Super Specialty Hospitals.		
3.	HLA Typing Report in transplant cases		

Signature and Stamp of MS/Dean/RD

Annexure - E

Proforma for ERT Cases:

Sl. No.	Information Required	Reply	Corresponding Page No. in TOC (Where document attached)
1.	Whether the prescribed drug is a generic or proprietary drug. In case propriety drug, then proprietary certificate be provided.		
2.	Whether any alternative/substitute drug is available of another brand or generic name. In case yes, rate quotation, proprietary certificate and lowest rate certificate be provided.		
3.	In ERT cases, Latest Progress report along with Mental and development assessment (IQ and DQ)		
4.	Whether Target Parameters achieved (like BOX 2 criteria), if applicable		
5.	Whether any alternative/substitute drug is available of another brand or generic name. In case yes, rate quotation and lowest rate certificate be provided.		
6.	Prescription & Opinion from Centre of Excellence (COE) attached (Y/N)		

Signature and Stamp of MS/Dean/RD

Annexure - F

Clinical Check list in addition to Annexure D (Thalassemia):

1. Complete diagnosis with mutation report	
2. Transfusion history mentioning a.Age at starting of regular transfusion b. Frequency of transfusion	
3. Chelation history mentioning a. Age starting of iron chelation, b. Type of chelating agent used, dose c. Response to chelation therapy	
4. HLA typing report of the prospective donor(s)	
5. Relation of the donor with the patient: -	

Signature and Stamp of Specialist

Annexure G

Clinical Check List in addition to Annexure D (Lymphoma/LeukaemiaHCT):

Baseline/at diagnosis:	
A. **For diagnosis and prognostication**	
1. CBC, peripheral smear	
2. Lymph node biopsy for histopathological evaluation and immune histo-chemistry report	
3. PETCT(whole body)/Other imaging method as indicated	
4. Bone marrow aspiration and biopsy report(in indicated c ases)	
5. Immunopheno typing by flow cytometry(in indicated cas es)	
6. Molecular/FISH panel for prognostication(in indicated c ases)	
B. Treatment:	
Case summary from treating physician stating	
1. Chemo-therapy protocol	
2. Number of cycles/phases	
3. Response to therapy	
C. Response assessment:	
PETCT(Whole body)/Other imaging method as indicated	
At Relapse:	
A. **For diagnosis and prognostication**	
1. CBC, peripheral smear	
2. Lymph node biopsy for histopathological evaluation and immune-histochemistry report	
3. PETCT(whole body)/Other imaging method as indicated	
4. Bone marrow aspiration and biopsy report(in indicated c ases)	
5. Immunophenotyping by flow cytometry(in indicated cas es)	
6. Molecular/FISH panel for prognostication(in indicated c ases)	
Treatment:	
Case summary from treating physician stating	
1. Treatmentsummaryofdenovodiseasementioningcomplete diagnosisincludingstage, riskgroup,treatmentreceivedinth e1st lineandresponsetotherapyinupfrontdisease	

2. Chemotherapy protocol used in relapsed phase	
3. Number of cycles/phases	
4. Response to therapy	
Response assessment:	
Bone marrow aspiration/MRD report	
For Haematopoietic Stem Cell Transplant:	
1. HLA typing report of the prospective donor	
2. Relation of the donor with the patient	

Signature and Stamp of Specialist

Annexure- H

Clinical Check List in addition to Annexure D(A plastic Anaemia):

At baseline:	
1. Clinical History:	
Whether denovoorno response to 1st line therapy or relapse If relapse, case summary from treating physician menti oning details of **1st line therapy** and response to 1st lin e therapy	
2. CBC, Reticulocyte count, Peripheral smear	
3. Bone marrow aspiration and biopsy report	
4. Convention alkaryo typing report(if available)	
5. Stress cytogenetics report(if<40years)	
6. Assessment for PNH clone by flow cytometry and FLARE	
7. HBsAg, Anti HCVIgM, HIV I and II	
8. USG(whole abdomen)	
9. Echocardiography	
10. ANA(byIFonHep2cell lines)	
For Haematopoietic Stem Cell Transplant:	
1. HLA typing report of the prospective donor(s)	
2. Relation of the donor with the patient	

Signature and Stamp of Specialist

Annexure- I

Proforma/Diary or Enzyme Replacement Therapy(ERT)to be maintained in ESI Hospital(Gaucher's Disease)

Photo of Patient

Name of Patient…….……Name of IP……Insurance No. …… Date ofBirthof patient……..……
Sex…….... Diagnosis……. Date ofDiagnosis……..…… Date of start of ERT……ERT advised by (name of hospital) ……

Sl. No.	Date of ERT	Name of Drug	Dose	Clinical status as on date Improving/same/deteriorating	Identity verified	Name & Signature of consultant

NOTE:

1. Signature of consultant to bed one on every visit.
2. Signature of Medical Superintendent at the time of sanction of the drug after ensuring correctness of the details filled in and to be forwarded to ESIC Hqrs. at the time of referring the case to High Cost Treatment Committee.
3. To be maintained at the referring ESI hospital (in concerned department & store) on a hard paper/sheet/folder. The same may be asked by ESIC Hqrs. Office at any time.

(Medical Superintendent/Dean)

Annexure- J

Clinical assessment for Gaucher's disease (At baseline, 6 months and thereafter yearly)

1	2	3	4	5	6	7	8	9	10	11	12
Date	Weight	Height	Liver	Spleen	Hemogram	Dexa	MRI Spine & FemoralNeck	Chito-triosidase	PET	HRCT	2D Echo

- **Monitoring of Sl. No. 2, 3, 4 & 5to be done every 6months.**
- **Monitoring of Sl. No. 7, 8 & 9 to be done yearly.**
- **Monitoring of Sl. No. 10, 11 & 12 to be done as per indication.**

(Name and Signature of Consultant/Specialist)

Annexure- K

Proforma/Diary for Enzyme Replacement Therapy (ERT) to be maintained in ESI Hospital (Fabry Disease)

Name of Patient…….Name of IP……Insurance No.…… Date of Birth of patient……Sex…….....Diagnosis……Date of Diagnosis…… Date of start of ERT……ERT advised by(name of hospital)……

Photo of Patient

Sl.No.	Date of ERT	Name of Drug	Dose	Clinical status as on date Improving /same/deteriorating	Identity verified	Name & Signature of consultant

NOTE:

1. Signature of consultant to be done on every visit.
2. Signature of Medical Superintendent at the time of sanction of the drug after ensuring correctness of the details filled in and to be forwarded to ESIC Hqrs. at the time of referring the case to High Cost Treatment Committee.
3. To be maintained at the referring ESI Hospital(in concerned department and store) on a hard paper/sheet/folder. The same may be asked by ESIC Hqrs. Office at any time.

Signature and Stamp of Specialist **(Medical Superintendent/Dean)**

Annexure- L

Clinical assessment for Fabry Disease (To be forwarded to Hqrs. every 6 months)

1	2	3	4	5	6	7	8	9	10	11
Date	Weight	Height	Symptoms(specify)	Hemogram	KFT/S.Elec	UrineProtein	Hearing/Visionassessment	Cardiacstatus	CNS	Others

- **Monitoring of 2,3,4,9,10 to be done on every visit.**
- **Monitoring of 5,6,7 to be done on base line and monthly visit. Monitoring of 8 and 11 to be done on base line and as required.**

(Name and Signature of Consultant/Specialist)

Annexure- M

Proforma/Diary for Enzyme Replacement Therapy (ERT)to be maintained in ESI Hospital Mucopolysacharidosis (MPS)

Photo of Patient

Name of Patient…….Name of IP……Insurance No.…… Date of Birth of patient……Sex……....Diagnosis…….Date of Diagnosis…… Date of start of ERT…… ERT advised by (name of hospital)……

Sl. No.	Date of ERT	Name of Drug	Dose	Clinical status as on date Improving/same/deterioratin g	Identity verified	Name & Signature of consultant

NOTE:

1. Signature of consultant to be done on every visit.
2. Signature of Medical Superintendent at the time of sanction of the drug after ensuring correctness of the details filled in and to be forwarded to ESIC Hqrs. at the time of referring the case to High Cost Treatment Committee.
3. To be maintained at the referring ESI hospital (in concerned department and store)on a hard paper/sheet/folder. The same may be asked by ESIC Hqrs. Office at any time.

Signature and Stamp of Specialist (Medical Superintendent)

Annexure- N

Clinical assessment for MPS(Atbaseline,6 months and thereafter yearly)

1	2	3	4	5	6	7	8	9	10
Date	Weight	Height	Liver	Spleen	Snoring	6minute walk test	3minutestairClimb test	Cardiac Status	Ophthalmological Examination

(Name and Signature of Consultant/Specialist)

Annexure- O

Clinical assessment for MPS(Atbaseline,6 months and thereafter yearly)

	1.	2.	3.	4.	5.	6.
Date	**PFT** **FEV1,FVC, FEV1/FVC,PEFR (Pred%)(Pred%) (Pred%)(Pred%)**	**Range of movements Shoulder flexion, Elbow extension, Knee extension**	**Polysomnography**	**HRCT Chest**	**2D Echo**	**Others**

- **Monitoring of 2 to 6 to be done every 6 monthly.**
- **Monitoring of 7 to12 to be done yearly.**
- **Monitoring of 13, 14 & 15 to be done as per indication.**

(Name and Signature of Consultant/Specialist)

Annexure- P

Proforma/Diary for Enzyme Replacement Therapy(ERT)to be maintained in ESIHospital(other than MPS/Gaucher's/Fabry's)

Photo of Patient

NameofPatient……NameofIP……
……InsuranceNo.……DateofBirthof patient……Sex……....Diagnosis……Date of Diagnosis…… Date of start of ERT…… ERT advised by(name of hospital)……

Sl. No.	Date of ERT	Name of Drug	Dose	Clinical status as on date Improving/same/deteriorating	Identity verified	Name & Signature of consultant

NOTE:

1. Signature of consultant to be done on every visit.
2. Signature of Medical Superintendent at the time of sanction of the drug after ensuring correctness of the details filled in and to be forwarded to ESIC Hqrs. at the time of referring the case to High Cost Treatment Committee.
3. To be maintained at the referring ESI hospital (in concerned department & store) on a hard paper/sheet/folder. The same may be asked by ESIC Hqrs. Office at any time.

Signature and Stamp of Specialist (Medical Superintendent)

Annexure- Q

Utilization certificate for Recurring High-cost Treatment cases (RC &NON-RC Drugs)

Name of the Patient:

Insurance no.:

Diagnosis.:

Age/Sex of the Patient:

Date of Issue:

Name of Dispensary/Hospital:

Photo of Patient

S. No.	Name of Medicine	Strength / Dose	Quantity Issued(mg/ml/vials etc.	Batch No	Expiry date	MRP	Frequency	Period of Use (From–To)	Remarks
1.									
2.									
3.									
4.									

Certified that the above medicines have been utilized for the concerned Patient

If required, empty strips / vials will be submitted.

Signature of the Patient & IP No.
Address and Contact No.:

Signature of the Specialist
Date:
Stamp:

Signature and Stamp of the MS

Annexure -R

VERIFICATION REPORT OF GENUINENESS OF BENEFICIARY

(To be completed by deputed ESIC Official as per directions of the Regional Director)

A. Particulars of IP/IW

1. Name of IP/IW .....
2. Insurance Number.....
3. Relevant Contribution Period: From ..... To .....

Photo of

Patient duly verified

B. Particulars of patient

4. Name of Patient .....
5. Relationship with IP/IW.....

C. Workplace details of IP/IW:

6. Name & Address of Workplace.....
   .....

D. Residential address:

7. Address of Residence .....
   .....

E. Verification of IP/IW: (To be filled by deputed ESIC official)

Sl. No.	Verification Point	Yes / No	Remarks
1.	Personal visit to workplace of IP/IW conducted		
2.	Photo verification of IP/IW at workplace		
3.	Employer confirmation obtained/on existence		
4.	Employment and contribution status verified for the corresponding contribution period		
5.	Verification of the IP identity documents and IP employment details, original attendance and wages registers, salary bank account statement, Aadhar Card, PAN Card etc.		

F. Verification of ESI beneficiary:(Applicable only if patient is NOT IP/IW)

Sl. No.	Verification Point	Yes / No	Remarks
1.	Personal visit to residence conducted		
2.	Identity of beneficiary verified		
3.	Relationship with IP / IW verified		
4.	Photo verification of beneficiary done		

5.	Beneficiary eligibility verified with reference to the corresponding contribution period		
6.	Verification of the documents: Aadhar Card, PAN Card etc.		
7.	Any specific observations:		

G. Declaration by deputed ESIC official

I hereby certify that I have personally carried out the above verification and that the identity, employment status, relationship, and eligibility of the IP / IW and/or ESI beneficiary have been verified, including confirmation that the verification covers the corresponding contribution period, and the same are found to be genuine and authentic.

s

Signature & Stamp of
Deputed Officer / Official

Countersigned by
Regional Director (RD) & Stamp

H. Employer certification

Name of Employer / Authorized Representative
.....

Signature & Stamp of the Employer

Note: This verification report is to be enclosed with the HCT Proforma.

Annexure- S

COST ESTIMATION FOR HIGH-COST MEDICINES (IF APPLICABLE)

A. Particulars of insured person / beneficiary

1. Name of IP / Beneficiary _____
2. Insurance No. (IP No.) _____
3. Age / Sex _____
4. ESIC Dispensary / Hospital _____

B. Medical details

Sl. No.	Particulars	Details
1.	Diagnosis	
2.	Name of High-Cost Medicine	
3.	Indication for Use	
4.	Emergency / Non-Emergency	
5.	Medicine Available in ESIC, Yes / No	
6.	If No, Reason for Outside Procurement	
7.	Available Strength (mg/ml , mg etc)	
8.	Dose per Cycle / Administration	
9.	Total No. of Cycles Planned	
10.	Expected Duration of Therapy	

C. Certification by treating specialist

I hereby certify that the above-mentioned high-cost medicine is essential for the treatment of the patient and is not available in DGRC of ESIC and there is no alternative substitute available in DGRC.

Signature & Stamp of Treating Specialist

D. Cost & treatment details (high-cost medicine)

Sl. No.	Particulars	Details
1	Cost per Vial / Unit (₹)	
2	Total No. of Cycles Completed till date & cumulative cost since the beginning.	
3	Total Estimated Cost for Remaining Cycles (₹)	

I hereby certify that the above-mentioned high-cost medicine is essential for the treatment of the patient and is not available in DGRC of ESIC and there is no alternative substitute available in DGRC.

Pharmacist **Store In-charge/DMS**

E. Recommendation by ESIC hospital/Medical College

This is the administrative approval from ESIC.

Recommended By

Signature & Stamp of Medical Superintendent/Dean

Annexure- T

Drug essentiality Certificate by Specialist/Faculty of Center of Excellence

CERTIFICATE

This is to certify that the drug _____ (generic name with strength and dosage form) is an essential drug for the management of _____ (indication / disease condition).

It is further certified that:

1. No alternative generic drug or biosimilar / bio-equivalent formulation of the above-mentioned drug is available in the market at present for the said indication.
2. The drug is clinically necessary and its use is justified in the best interest of patient care.
3. The undersigned has no conflict of interest, financial or otherwise, in relation to the above-mentioned drug.
4. There has been no financial disclosure, direct or indirect, in the form of:

- Research grants
- Sponsored studies or trials
- Consultancy, honorarium, or speaker fees
- Any other monetary or non-monetary benefit

from any pharmaceutical company or related entity concerning the said drug.

This certificate is issued for official and administrative purposes.

Name of the Certifying Authority: _____

Designation: _____

Department / Specialty: _____

Institution / Hospital: _____

Signature: _____

Date: _____

Official Seal: _____