MODERN TREATMENTS IN INDIA AND GLOBALLY: A CLINICAL LANDSCAPE

Introduction

This document serves as a comprehensive research providing an overview of **modern treatments** in healthcare, with the objective of mapping their clinical applications, regulatory status, and global as well as Indian adoption. It is intended for medical researchers, clinicians, health policy planners, and insurance strategists to better understand the evolving landscape of advanced medical interventions. In addition to providing an overview on Modern Treatments in India, the document provides comprehensive details on CAR-T Therapies and Robotic Surgeries

Scope

The scope of this research includes treatment modalities recognized under IRDAI's definition of modern treatments, with primary focus on

- Immunotherapies
    - CAR-T Therapies only
    - Checkpoint Inhibitors (Brief Overview)
    - Cytokines (Brief Overview)
    - Monoclonal Antibodies (Brief Overview)
    - Cancer Vaccines (Brief Overview)
- Robotic Surgeries

Approach

For each treatment category, this document explores:

- **Clinical Applications** — Conditions and disease areas treated
- **Mechanism & Procedure** — How the treatment is delivered
- **Regulatory Status** — Approvals from FDA, EMA, CDSCO, and other bodies
- **Global & Indian Adoption** — Market availability, infrastructure, and capacity
- **Limitations & Considerations** — Clinical, logistical, and economic factors

Modern Treatment: Introduction & Regulatory Classification

A Modern Treatment is any procedure, therapy, or technology that significantly departs from conventional approaches in terms of methodology, precision, or personalization, and typically:

- Requires specialized infrastructure or advanced technological platforms
- Has received conditional, accelerated, or full regulatory approvals
- Is supported by growing clinical evidence and peer-reviewed research
- Requires specialized clinical expertise and multidisciplinary management

Importance in Healthcare

Modern treatments represent the most advanced level of medical innovation currently available. They have the potential to:

- **Improve patient outcomes** by offering higher success rates, faster recovery times, fewer complications, or targeted disease control compared to conventional treatments.
- **Deliver more precise interventions** by leveraging technology such as robotics, molecular targeting, or image-guided navigation to reduce damage to healthy tissue and tailor therapy to the individual's biology.
- **Offer curative potential in some cases**, especially in areas like gene therapy, CAR-T therapy, and certain organ transplantation or regenerative medicine approaches, where diseases previously considered untreatable may now be reversed or cured.

However, these opportunities are balanced by key challenges:

- **Accessibility** — Many modern treatments require highly specialized facilities and trained teams, limiting availability to select centers, often in metropolitan or developed regions.
- **Cost** — These therapies frequently involve high upfront expenses for devices, consumables, manufacturing, and specialized care, making them financially challenging for patients and healthcare systems.
- **Policy Integration** — Coverage decisions, reimbursement models, and inclusion in public or private insurance schemes require careful policy planning to ensure equitable access without jeopardizing financial sustainability.

Regulatory Classification as per IRDAI

The Insurance Regulatory and Development Authority of India (IRDAI), through its Guidelines on Standardization in Health Insurance, mandates that all insurers cover modern treatment methods under hospitalization expenses if these are **medically necessary** and **clinically appropriate**. This means that when a modern treatment is supported by evidence, prescribed by a qualified medical professional, and relevant to the patient's condition, it must be considered eligible for coverage, subject to policy terms.

This includes procedures like:

Treatment Type	Example
Robotic Surgeries	Robotic-assisted prostatectomy, hysterectomy
Stem Cell Therapy	For hematological conditions like leukemia
Oral Chemotherapy	Used for various cancers (e.g., imatinib for CML)
Immunotherapy	Monoclonal antibodies for cancer and autoimmune disorders
Balloon Sinuplasty	Sinus-related conditions
Deep Brain Stimulation	Parkinson's disease
HIFU (High-Intensity Focused Ultrasound)	Prostate cancer, uterine fibroids
Intraoperative Neuro Monitoring (IONM)	Spine or brain surgeries
Stereotactic Radiosurgery	Brain tumors (e.g., Gamma Knife, CyberKnife)
Bronchial Thermoplasty	Severe asthma
Targeted Therapy	Cancer (e.g., trastuzumab for HER2+ breast cancer)
Proton Beam Therapy	Pediatric tumors, brain tumors

Coverage Criteria & Caveats

To be eligible for insurance coverage under IRDAI guidelines, modern treatments must meet the following:

- **Medical Necessity**: Must be prescribed as part of a medically necessary treatment protocol.
- **Regulatory Approval**: Should be approved by global (FDA, EMA) or national regulators (CDSCO).
- **Transparency in Policy Wording**: Insurers must clearly mention coverage or exclusions of such treatments in their product brochures and policy contracts.

Modern treatments may not be covered under the following circumstances:

- If the treatment is considered **experimental or investigational**.
- If regulatory approvals are **pending** or the therapy is not yet included in standard clinical guidelines.
- If the **hospital lacks adequate infrastructure** or trained personnel to perform the treatment safely.

Drug Approval Bodies

- **US Food and Drug Administration (US FDA)**
- **Central Drugs Standard Control Organization (CDSCO)**
- **Drug Controller General of India (DCGI)**

Regulatory Approval Status

Treatment Type	FDA Approval	CDSCO / DCGI Approval	Comments
Robotic Surgery	✅	✅	Approved for multiple indications
Immunotherapy	✅	✅	Many drugs approved (nivolumab, pembrolizumab)
Targeted Therapy	✅	✅	Drug-specific approvals (e.g., imatinib, erlotinib)
Proton Therapy	✅	✅	Approved centers in India (Apollo, HCG)
HIFU	✅	✅	Approved for specific indications
Stem Cell Therapy	❌ for most	❌ (unless for hematopoietic reconstitution)	
Bronchial Thermoplasty	✅	Limited	Some insurance covers under prior approval

Stem Cell Therapy is **not approved by CDSCO** except for bone marrow transplantation for hematological conditions.

Modern Treatments Under Trial

Treatment	Status	Use Case
CRISPR gene editing	Trial	Sickle cell, beta thalassemia
CAR-T Cell Therapy	Trial/limited approval	Some cancers (leukemia, lymphoma)
Nanomedicine based therapies	Trial	Drug delivery for cancer
Stem cells for heart failure, diabetes	Trial	Not standard of care
mRNA therapies (non-COVID)	Trial	Cancer, genetic disorders

Immunotherapy: Overview

Immunotherapy is a **type of modern treatment** that uses the body's **own immune system** to fight diseases, particularly **cancer**. It works by either:

- **Stimulating the immune system** to work harder or smarter,
- Or by **introducing man-made immune system components**, like **monoclonal antibodies**.

Types of Immunotherapies

Type	Drugs/Examples	Mechanism
Checkpoint Inhibitors	Pembrolizumab, Nivolumab, Atezolizumab	Block PD-1/PD-L1 to enhance T-cell attack
Cytokines	Interleukin-2, Interferon-alpha	Stimulate immune cell proliferation
Monoclonal Antibodies	Rituximab, Trastuzumab	Bind specific antigens on cancer cells
Cancer Vaccines	HPV Vaccine, Sipuleucel-T	Prevent or treat cancer via immunity
CAR-T Therapy	Tisagenlecleucel, Axicabtagene	Genetically engineered T-cells

Cancer types and Indications for Drugs

The below drugs are available for the conditions listed along with the indication:

Cancer Type	Immunotherapy Drug	Indication
Non-Small Cell Lung Cancer (NSCLC)	Nivolumab, Pembrolizumab	Advanced/metastatic
Melanoma	Nivolumab, Ipilimumab	Advanced/metastatic
Renal Cell Carcinoma (RCC)	Nivolumab, Atezolizumab	Advanced
Hodgkin's Lymphoma	Nivolumab, Pembrolizumab	Relapsed/refractory
Triple-Negative Breast Cancer (TNBC)	Atezolizumab + chemo	PD-L1 positive tumors
HER2+ Breast Cancer	Trastuzumab, Pertuzumab	Adjuvant and metastatic
Colorectal Cancer (MSI-H)	Pembrolizumab	Metastatic, high microsatellite instability
Head and Neck Squamous Cell Carcinoma (HNSCC)	Nivolumab	Platinum-refractory
Bladder Cancer	Atezolizumab, Durvalumab	Locally advanced/metastatic
Prostate Cancer	Sipuleucel-T	Advanced, resistant
Cervical Cancer	Pembrolizumab	PD-L1 positive, metastatic/recurrent
Hepatocellular Carcinoma (HCC)	Atezolizumab + Bevacizumab	Unresectable

Key Drugs available in India and their Approvals

Drug Name	Brand Name(s)	Indication	FDA Approval	CDSCO Approval
Nivolumab	Opdivo	NSCLC, RCC, HNSCC, Melanoma, Hodgkin's Lymphoma	✅	✅
Pembrolizumab	Keytruda	NSCLC, Melanoma, MSI-H or dMMR cancers, Cervical, Bladder cancer	✅	✅
Trastuzumab	Herceptin / Biosimilars	HER2+ breast cancer, gastric cancer	✅	✅
Atezolizumab	Tecentriq	NSCLC, TNBC, Bladder, HCC	✅	⚠️ (Selectively Approved)
Durvalumab	Imfinzi	Stage III NSCLC	✅	✅
Rituximab	MabThera / Ritucad	NHL, CLL, autoimmune diseases (RA)	✅	✅
Ipilimumab	Yervoy	Melanoma, combination with Nivolumab	✅	✅
CAR-T therapies(e.g., Kymriah)	-	B-cell leukemia, lymphoma	✅	⚠️ (Limited Approval)

Car-T Therapy

What is CAR-T Therapy?

CAR-T therapy is a type of cell-based gene therapy. It involves collecting T-cells from a patient, genetically engineering them to express chimeric antigen receptors (CARs) that target specific proteins on cancer cells, expanding these modified cells in a lab, and reinfusing them into the patient.

Administration of CAR-T Therapy

1. **Leukapheresis**: Extraction of patient T-cells.
2. **Gene Modification**: T-cells are reprogrammed using viral vectors.
3. **Expansion**: Modified T-cells are multiplied.
4. **Conditioning Therapy**: Chemotherapy before CAR-T infusion.
5. **Infusion**: Reintroduction of CAR-T cells into the patient.
6. **Monitoring**: For side effects like Cytokine Release Syndrome (CRS), neurotoxicity.

Indications for CAR-T Eligibility

- Refractory or relapsed B-cell cancers
- Failure of at least 2 lines of systemic therapy
- Performance score (ECOG) ≤ 2
- Absence of uncontrolled infections
- Normal organ function tests

Use Cases of CAR-T Therapy

- Hematologic malignancies such as:
  - Acute Lymphoblastic Leukemia (ALL)
  - Diffuse Large B-cell Lymphoma (DLBCL)
  - Mantle Cell Lymphoma (MCL)
  - Multiple Myeloma
  - Follicular Lymphoma

Globally Approved CAR-T Therapies

Brand Name	Generic Name	Target Antigen	Approved Indications	FDA Approval
Kymriah	Tisagenlecleucel	CD19	B-cell ALL, DLBCL	2017
Yescarta	Axicabtagene ciloleucel	CD19	LBCL, PMBCL	2017
Tecartus	Brexucabtagene autoleucel	CD19	MCL, Adult ALL	2020
Breyanzi	Lisocabtagene maraleucel	CD19	LBCL, FL, SLL	2021
Abecma	Idecabtagene vicleucel	BCMA	Refractory Multiple Myeloma	2021
Carvykti	Ciltacabtagene autoleucel	BCMA	Multiple Myeloma (after ≥4 therapies)	2022

CAR-T Therapy in India and CDSCO Approval

Brand Name	Developer	Target Antigen	Indications	CDSCO Status	Year
NexCAR19	ImmunoACT (IIT Bombay)	CD19	B-cell Leukemia & Lymphoma	Approved	2023
Qartemi	Immuneel Therapeutics	CD19	B-cell Non-Hodgkin Lymphoma	Approved	2025

Pricing and Infrastructure

- **India**: Approx. $50,000–$60,000 (INR 40–50 lakhs)
- **USA**: Approx. $400,000–$500,000
- **Treatment Centers in India**:
  - Immuneel Therapeutics, Bangalore
  - Tata Memorial Centre
  - AIIMS, Delhi

Limitations

- Side Effects: CRS, neurotoxicity
- Not effective for most solid tumors yet
- High manufacturing complexity and cost

OT and Infrastructure Protocols for CAR-T Therapy

CAR-T therapy is not a surgical procedure, so it doesn't require traditional operation theater (OT) environments. However, **strict infrastructure protocols** are essential across the **cell collection**, **processing**, and **administration** phases to ensure safety, sterility, and regulatory compliance. These protocols are more aligned with **cleanroom**, **GMP**, and **transplant-like care** rather than surgical OTs.

Global Standards and Protocols

Phase	Key Infrastructure & Protocols
Leukapheresis	- Performed in an apheresis unit (not OT) - Requires Class 100,000 (ISO 8) cleanroom setup
Cell Processing	- Requires GMP-compliant cleanroom (ISO 7 or better) - HEPA filters, sterile gowning areas
Infusion	- Administered in bone marrow transplant (BMT) or oncology ward - ICU backup recommended
Monitoring	- CRS and neurotoxicity monitoring in specialized cancer/ICU unit for 7–14 days post-infusion

Personnel Required:

Hematologist/Oncologist, Transfusion specialist, Trained ICU staff, GMP lab technicians.

Regulations Followed:

- FDA 21 CFR Part 1271 (U.S.)
- EMA GMP Annex 1 (Europe)
- FACT-JACIE Accreditation (voluntary but followed by major centers)

Indian Context and Protocols

India's CAR-T protocols are developing rapidly, modeled on global standards but adapted to local capabilities.

Phase	Indian Protocol Adaptations
Leukapheresis	- Conducted at tertiary centers with apheresis capability (e.g., Tata Memorial, AIIMS)
Cell Processing	- NexCAR19 & Qartemi use in-house GMP facilities (ISO 7 cleanroom, viral vector safety)
Infusion	- Performed in BMT-like oncology wards with ICU access; no traditional OT use
Monitoring	- CRS grading as per ASTCT guidelines; cytokine testing and tocilizumab availability mandatory

CDSCO Guidelines: Requires compliance with:

- Schedule M for GMP facilities
- NABL/NABH accreditation for clinical centers
- Local Institutional Ethics Committee (IEC) approval

Key Distinctions from Traditional OT Protocols

Factor	Traditional OT	CAR-T Therapy Facility Requirements
Environment	Sterile surgical suite	GMP-certified cleanroom & ICU/oncology ward
Use of Anesthesia	Yes	No (only premedication and supportive care)
Invasive Procedures	Yes	No (infusion only, similar to blood transfusion)
Staff Involvement	Surgeons, anesthetists	Oncologists, hematologists, ICU nurses
Duration in Facility	Short (hours)	Long (may need hospital stay 1–2 weeks post infusion)

Administration & Dosage Guidelines – Car-T Therapy

Name of treatment	Condition(s)	Indication for use (specific condition, severity / stage / sequence)	Indication for hospitalization / monitoring	Dosage form & typical duration	Principal adverse reactions / safety notes
KYMRIAH (tisagenlecleucel)	• B-cell acute lymphoblastic leukemia (B-ALL) in pediatric/young adults; • Relapsed/Refractory large B-cell lymphoma (DLBCL) and follicular lymphoma (accelerated approval).	**Peds/young adult B-ALL**: • For refractory disease or ≥2nd relapse (≤25 yrs). **DLBCL/FL (adult)**: • Relapsed/refractory after ≥2 lines systemic therapy (includes DLBCL NOS, high-grade B-cell lymphoma, DLBCL from FL) *not for primary CNS lymphoma.*	**Inpatient** for infusion and immediate post-infusion monitoring due to risk of CRS and neurotoxicity; close monitoring (often 7–14 days) and ICU access available if severe CRS/neurologic events.	Cryopreserved autologous cell suspension in 1–3 infusion bags Dosing: • Pediatrics ≤50 kg: 0.2–5.0×10^6 CAR+ T cells/kg; >50 kg: up to 0.1–2.5×10^8 total. • Single infusion; supportive lymphodepletion prior to infusion.	• **CRS (can be severe/fatal)** • neurologic toxicities/ICANS • prolonged cytopenias • infections • anaphylaxis • secondary T-cell malignancies reported post-marketing. • Tocilizumab availability required; premedicate (acetaminophen + H1 blocker).
YESCARTA (axicabtagene ciloleucel)	• Adult relapsed/refractory large B-cell lymphoma (LBCL) including DLBCL, PMBCL, high-grade B-cell lymphoma, DLBCL transformed from FL; • Accelerated approvals in FL after ≥2 lines.	Indicated for patients • refractory to, or • relapsing ≤12 months after first-line chemoimmunotherapy, • or after ≥2 systemic lines. *Not for primary CNS lymphoma.*	**Inpatient** for infusion and early monitoring; observation for CRS and neurotoxicity; facilities must be certified; tocilizumab available. Typical monitoring period several days to 2 weeks depending on course.	• Suspension infusion (~68 mL) containing target dose 2×10^6 CAR+ viable T cells/kg (max 2×10^8). • Single infusion after lymphodepletion (cyclophosphamide + fludarabine).	**CRS (may be severe/fatal)** neurologic toxicities (encephalopathy, seizures, confusion) cytopenias, infection risk of secondary hematologic malignancies. Premedication and availability of tocilizumab required.
TECARTUS (brexucabtagene autoleucel)	• Adult relapsed/refractory mantle cell lymphoma (MCL); • Adult relapsed/refractory B-cell precursor ALL (different indications).	**MCL**: accelerated approval for patients with relapsed/refractory disease following prior therapies. **B-cell precursor ALL (adult)**: for relapsed/refractory disease.	**Inpatient** monitoring post-infusion for CRS/neurotoxicity; certified facility administration required; ICU backup for severe events.	Suspension (~68 mL). Dosing: • MCL ~2×10^6 CAR+ T cells/kg (max 2×10^8); • ALL dosing ~1×10^6/kg (max 1×10^8). • Single infusion after lymphodepletion (cyclophosphamide + fludarabine).	**CRS** **neurologic toxicities** prolonged cytopenias infections risk of secondary malignancies. Tocilizumab must be available; premedicate (acetaminophen + antihistamine).
BREYANZI (lisocabtagene maraleucel)	• Relapsed/refractory large B-cell lymphoma (LBCL) including DLBCL, PMBCL, transformed FL • Certain approvals for CLL/SLL, FL, and MCL in later lines (accelerated approvals as applicable).	Indicated for adult LBCL patients refractory or relapsed ≤12 months after first-line therapy or after ≥2 lines (with details per label) *some indications require prior exposure to targeted agents.*	**Inpatient** monitoring for CRS/neurologic events; REMS-certified facility in many jurisdictions; monitoring intensity depends on local protocol but typically several days of inpatient observation.	Cell suspension in 1–4 vials (CD8/CD4 composition). Dosing examples: • LBCL 50–110×10^6 CAR+ cells (depending on prior lines); *Some regimens use 90–110×10^6.* • Single infusion after lymphodepletion (fludarabine + cyclophosphamide).	**CRS**, **neurotoxicity (ICANS)**, cytopenias, infections, increased risk of secondary hematologic malignancies; risk of life-threatening infections. Tocilizumab availability required; premedication recommended.
ABECMA (idecabtagene vicleucel)	• Relapsed/refractory multiple myeloma in adults after prior therapies (IMiD,	Indicated for adult r/r multiple myeloma after at least 3 prior lines including the classes listed.	**Inpatient** for infusion and monitoring for CRS/neurotoxicity; close follow-up for prolonged cytopenias and infections; manage per institutional CAR-T protocols.	Cryopreserved suspension; dose range: • 300–510×10^6 CAR+ viable T cells	**CRS** (can be severe/fatal), **neurotoxicity**, prolonged cytopenias, HLH/MAS potential, infections, and potential secondary hematologic malignancies. Avoid

Name of treatment	Condition(s)	Indication for use (specific condition, severity / stage / sequence)	Indication for hospitalization / monitoring	Dosage form & typical duration	Principal adverse reactions / safety notes
	proteasome inhibitor, and anti-CD38 antibody).			• Single infusion following lymphodepletion (cyclophosphamide + fludarabine).	prophylactic steroids; tocilizumab available.
CARVYKTI (ciltacabtagene autoleucel)	• Relapsed/refractory multiple myeloma after prior lines (varies by label: after ≥1 line including PI and IMiD and refractory to lenalidomide in updated indications).	Indicated for adult r/r multiple myeloma after specified prior regimens *check latest label for exact line-of-therapy requirement in a jurisdiction.*	**Inpatient** administration with monitoring for CRS/neurotoxicity and cytopenias; certified facility and post-infusion follow-up required.	Intravenous infusion (single bag). Dose example per label: • 0.5–1.0×10^6 CAR+ T cells/kg (max 1×10^8) or per product vial formulation; • lymphodepletion prior to infusion (cyclophosphamide + fludarabine).	**CRS**, **neurotoxicity**, cytopenias, infections, GI symptoms, possible coagulopathy; hematologic lab abnormalities frequent. Tocilizumab requirement and supportive care per label.
NexCAR19 (actalycabtagene autoleucel — India)	• Relapsed/refractory CD19-positive B-cell lymphomas and B-cell acute lymphoblastic leukemia (B-ALL).	Indicated for patients ≥15 years with relapsed/refractory B-cell lymphomas and B-ALL after prior therapies as per local label *exclusions: primary CNS lymphoma and active CNS disease (treated history may be acceptable).*	**Inpatient** infusion at accredited centers with monitoring for CRS and neurotoxicity; tocilizumab and anakinra availability recommended; verify facility/ICU access.	Cryopreserved cell suspension in infusion bag (100 mL) • containing ~1×10^8 to 2×10^9 CAR-T cells; • Dosing stated ≥5 million CAR+ T cells/kg up to a max of 2×10^9 in single infusion; • lymphodepletion (cyclophosphamide + fludarabine) before infusion.	**CRS**, **neurotoxicity**, prolonged cytopenias, infections; specific safety management guidance includes tocilizumab/anakinra for CRS; pregnancy contraindicated; not for active CNS involvement.
Qartemi (varnimcabtagene autoleucel / var-cel — Immuneel)	• Adult relapsed/refractory B-cell Non-Hodgkin Lymphoma (B-NHL) / relapsed/refractory LBCL per label.	Indicated for adults with relapsed/refractory B-NHL after prior lines of therapy as per the product label and national approvals **To be prescribed by oncologists only.**	**Inpatient** infusion with monitoring for CRS and neurotoxicity; product administered in fractions (3 infusions) per label — close observation required after each fraction.	• Suspension for infusion split into three fractions (approx. 30 mL per bag): 10% / 30% / 60% split; • dose range 0.1×10^6 to 5×10^6 CAR+ T cells/kg (administered in three fractions). • Lymphodepletion prior to infusion.	Reported/anticipated: **CRS**, **neurotoxicity**, cytopenias, infections; early data reports favorable ORR with manageable safety profile but monitoring and tocilizumab availability required. Local published trial data and IMAGINE trial reports are referenced by the manufacturer.

Key notes

- **Hospitalization is standard** for all commercial CAR-T infusions because of the **risk of CRS and neurotoxicity. For certain cases, ICU Admission maybe required depending on the symptoms presented.**
- **Dose & formulation**: All products are supplied as autologous cryopreserved cell suspensions, in a single bag or multiple vials, administered once (or sometimes fractioned as with Qartemi) after lymphodepleting chemotherapy
- **Principal adverse events** across the class are consistent: **CRS**, **immune effector neurotoxicities (ICANS)**, **prolonged cytopenias**, and **infections**

Contraindications (Absolute and Relative)

CAR-T Therapy	Conditions Treated	Absolute Contraindications	Relative Contraindications
KYMRIAH (Tisagenlecleucel)	Pediatric/young adult r/r B-cell ALL; Adult r/r DLBCL, FL	Active CNS malignancy; Pregnancy or breastfeeding; Known hypersensitivity to product components; Unresolved uncontrolled infection	Prior allogeneic stem cell transplant <4 months; Organ dysfunction (cardiac EF <40%, severe lung disease); Active GVHD; Cytopenias

CAR-T Therapy	Conditions Treated	Absolute Contraindications	Relative Contraindications
YESCARTA (Axicabtagene Ciloleucel)	Adult r/r LBCL (DLBCL, PMBCL, FL3B); r/r FL	Primary CNS lymphoma; Active CNS involvement; Hypersensitivity to product; Uncontrolled infection	Cardiac dysfunction (EF <40%), pulmonary insufficiency, elderly frailty, high tumor burden (risk of severe CRS)
TECARTUS (Brexucabtagene Autoleucel)	Adult r/r Mantle Cell Lymphoma (MCL); r/r B-ALL	Active CNS leukemia; Uncontrolled infection/sepsis; Known hypersensitivity; Pregnancy	Organ impairment (renal/hepatic/cardiac); Poor ECOG performance; Cytopenias
BREYANZI (Lisocabtagene Maraleucel)	Adult r/r LBCL, CLL/SLL, FL, MCL	Active CNS malignancy; Uncontrolled infection; Hypersensitivity; Pregnancy	High tumor burden, older age, cardiac impairment, prior CAR-T exposure
ABECMA (Idecabtagene Vicleucel)	Adult r/r Multiple Myeloma	Pregnancy; Active CNS involvement; Hypersensitivity to components; Uncontrolled infection	Cytopenias, advanced age/frailty, cardiac dysfunction, prior BCMA therapy
CARVYKTI (Ciltacabtagene Autoleucel)	Adult r/r Multiple Myeloma	Pregnancy; Active CNS involvement; Hypersensitivity; Active uncontrolled infection	Older age, frailty, renal impairment, residual neuropathy
NexCAR19	r/r B-cell Lymphomas, r/r B-ALL	Active CNS disease; Active CNS malignancy; Pregnancy/lactation; Known hypersensitivity	Prior CAR-T, high tumor burden, older age, borderline organ function
Qartemi	r/r B-cell Non-Hodgkin Lymphoma (B-NHL)	Pregnancy; Active infection; Hypersensitivity; Active CNS involvement	Cytopenias, prior stem cell transplant, borderline cardiac/renal status

Position Statement (Sample)

Condition / Indication	Approved CAR-T Product(s)	Next-Best Alternative (Conventional Therapy)	Which Is Better (Clinical / Economic)	Published QALY Gain	Evidence Summary	Suggested Claims Position
r/r B-cell ALL (Paediatric / YA)	TISAGENLECLEUCEL (KYMRIAH)	Blinatumomab / Inotuzumab Ozogamicin / Allo-HSCT	**CAR-T clinically superior** (> 80 % ORR; cost-effectiveness borderline)	QALY ≈ 3–8	Durable remissions; curative potential in 40–50 % vs 10 % chemo	**Payable if all Conditions and indications are met**
r/r DLBCL / LBCL	AXICABTAGENE CILOLEUCEL (YESCARTA); LISOCABTAGENE MARALEUCEL (BREYANZI)	Salvage chemo ± auto-SCT ; Polatuzumab + Rituximab	**CAR-T better clinically; economic value borderline**	QALY 1.7–3.6;	Significant survival improvement vs chemo	**Payable if all Conditions and indications are met**
r/r MCL (Mantle Cell Lymphoma)	BREXUCABTAGENE AUTOLEUCEL (TECARTUS)	BTK inhibitors (ibrutinib / acalabrutinib); Benda-R combo	**CAR-T clinically superior; limited CE data**	QALY ≈ 1.8–2.4 ;	High CR (~70 %); CE uncertain	**Payable if all Conditions and indications are met**
r/r Multiple Myeloma	IDECABTAGENE VICLEUCEL (ABECMA); CILTACABTAGENE AUTOLEUCEL (CARVYKTI)	Pomalidomide / Daratumumab combos; bispecific Ab	**CAR-T clinically better but not cost-effective**	QALY ≈ 2–2.5;	Deep responses; ICER above threshold	**Payable if all Conditions and indications are met**
r/r Follicular / CLL / SLL	LISOCABTAGENE MARALEUCEL (BREYANZI)	BTK or PI3K inhibitors / Chemo-immunotherapy	**CAR-T potentially better clinically; insufficient economic data**	QALY 1.2–1.9;	Early data promising but uncertain	**Payable if all Conditions and indications are met**

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Sample Adjudication Checklist

Stage I: Pre-Authorization

Confirm Patient Identity and Eligibility

- Policy Details (Active / Inactive)
- Waiting Periods
- Exclusions (if applicable)

Confirm Medical Necessity

- Diagnosis confirmed by pathology / flow cytometry / molecular tests.
- Previous therapy history documented (lines of therapy, dates, responses).
- Rationale that CAR-T is indicated per product label/approved indication or documented guideline (e.g., relapsed / refractory after X lines).

Regulatory & facility checks

- Product approved in jurisdiction (CDSCO/FDA) for indication OR patient enrolled in an approved clinical trial. Cite approval evidence.
- Treating centre accredited (NABH/FACT-JACIE/NABL) and listed as CAR-T capable (apheresis, GMP or verified manufacturing partner, ICU, BMT unit).
- Confirm facility has REMS/REMS-equivalent certifications where required and staff trained on CAR-T management.

Cost estimate & itemization

- Obtain a detailed estimate: leukapheresis, manufacturing / vector costs, bridging therapy, lymphodepletion chemo, infusion fees, ICU, tocilizumab/anakinra, transfusions, supportive meds, physiotherapy, follow-up visits.
- Ensure device/manufacturing fee and hospital fee are separately itemized.

Safety readiness

- Confirm availability of tocilizumab (and anakinra if required) and ICU backup.
- Pre-infusion labs, pregnancy test (if applicable), infectious disease screen per label.

Documentation to collect

- Full clinical summary, prior treatment records, pathology, PET/CT or relevant imaging, performance status (ECOG), informed consent (including risks of CRS/ICANS), pre-auth request, cost estimate, facility credential list, product lot/manufacturer details (if available).

Stage II: Day of Infusion / Admission Review

- Confirm lymphodepletion completed per protocol (agent/dates) and no contraindication to infusion.
- Verify product chain-of-identity (sample ID / lot / infusion bag ID) and patient identity at bedside.
- Confirm premedication done (acetaminophen ± H1 antihistamine) per label.
- Confirm presence of tocilizumab, emergency drugs and ICU team on standby.

Stage III: Post-Infusion Monitoring (claims perspective)

- Inpatient monitoring required by label
- Document occurrences of CRS/ICANS and interventions (tocilizumab doses, corticosteroids, ICU admission, mechanical ventilation, vasopressors, anakinra).
- Capture use of supportive resources: transfusions, antibiotics, growth factors, imaging, dialysis, prolonged hospitalization or rehospitalisation within 30/90 days.
- For severe toxicity, obtain ICU notes, ventilator records, vasopressor charts, and cytokine therapy records.

Adjudication Rules / Red Flags

- Red flag if treating centre lacks documented CAR-T capability (apheresis + certified manufacturing path + ICU).
- Red flag for missing product identity documentation (bag IDs, manufacturer paperwork).
- Require justification if infusion is outpatient or very short stay (less than label-recommended monitoring), unless local protocol/report supports safe outpatient use.
- Cost control: validate expensive line items (manufacturing fee, repeat infusions, bridging therapy) against market benchmarks and pre-auth estimate.

Checkpoint Inhibitors

What are Checkpoint Inhibitors?

Checkpoint inhibitors are monoclonal antibodies that block immune checkpoint pathways (PD-1, PD-L1, CTLA-4) that normally suppress T-cell activity. By inhibiting these pathways, they remove inhibitory signals ("immune brakes") and allow T-cells to attack tumor cells.

Administration

- Usually **intravenous infusion**
- Administered **every 2–6 weeks depending on drug**
- Treatment duration often **until disease progression or unacceptable toxicity**

Commonly Treated Conditions:

- Melanoma
- Non-small cell lung cancer (NSCLC)
- Renal cell carcinoma
- Hodgkin lymphoma
- Head and neck cancers
- Urothelial carcinoma
- Hepatocellular carcinoma
- MSI-H/dMMR cancers

Common Limitations for Checkpoint Inhibitors

- Biomarker dependency - Many indications require PD-L1 expression, MSI-H status, or tumor mutational burden testing before use
- Delayed onset of response - immunotherapy responses may take weeks to months
- Immune-related adverse events - Can cause autoimmune toxicities affecting lungs, liver, thyroid, colon, skin
- Risk of severe immune toxicity - Rare but serious complications such as pneumonitis, myocarditis, colitis
- Long treatment duration - Therapy may continue until disease progression or unacceptable toxicity

Globally Approved Treatments

Brand Name	Generic Name	Target Antigen	Approved Indications	FDA Approval
Keytruda	Pembrolizumab	PD-1	Melanoma, NSCLC, cervical cancer, gastric cancer, urothelial carcinoma, Hodgkin lymphoma, MSI-H or dMMR Colorectal Cancer, Bladder cancer	Approved
Opdivo	Nivolumab	PD-1	Melanoma, NSCLC, renal cell carcinoma, Hodgkin lymphoma, bladder cancer	Approved
Yervoy	Ipilimumab	CTLA-4	Metastatic melanoma	Approved
Tecentriq	Atezolizumab	PD-L1	NSCLC, urothelial carcinoma, breast cancer	Approved
Imfinzi	Durvalumab	PD-L1	NSCLC, small cell lung cancer	Approved
Bavencio	Avelumab	PD-L1	Merkel cell carcinoma, urothelial carcinoma	Approved
Libtayo	Cemiplimab	PD-1	Cutaneous squamous cell carcinoma	Approved

Treatments available in India and CDSCO Approval

Brand Name	Generic Name	Target Antigen	Approved Indications	CDSCO Approval
Keytruda	Pembrolizumab	PD-1	NSCLC, melanoma, head and neck cancer, Hodgkin lymphoma, MSI-H or dMMR Colorectal Cancer, Bladder cancer	Approved
Opdivo	Nivolumab	PD-1	NSCLC, renal cell carcinoma, bladder cancer	Approved
Tecentriq	Atezolizumab	PD-L1	NSCLC, breast cancer	Approved
Imfinzi	Durvalumab	PD-L1	NSCLC	Approved
Yervoy	Ipilimumab	CTLA-4	Melanoma	Approved
Bavencio	Avelumab	PD-L1	Merkel cell carcinoma, urothelial carcinoma	Approved

Name of treatment	Condition(s)	Indication for use (specific condition, severity / stage / sequence)	Indication for hospitalization / monitoring	Dosage form & typical duration	Principal adverse reactions / safety notes
Pembrolizumab	• Melanoma, NSCLC, cervical cancer, head & neck cancers, gastric cancer, urothelial carcinoma, Hodgkin lymphoma, MSI-H or dMMR Colorectal Cancer, Bladder cancer	PD-L1 expressing tumors, metastatic disease, or after failure of chemotherapy depending on indication *Can also be used as first line of treatment for colorectal cancer*	Infusion center monitoring; immune-related toxicity surveillance	• IV infusion; 200 mg every 3 weeks OR 400 mg every 6 weeks	• Immune-mediated pneumonitis, colitis, hepatitis, endocrinopathies
Nivolumab	• Melanoma, NSCLC, renal cell carcinoma, Hodgkin lymphoma, bladder cancer	Metastatic or recurrent disease; often after prior therapy or as combination therapy	Infusion monitoring required	• IV infusion; 240 mg every 2 weeks OR 480 mg every 4 weeks	Pneumonitis, hepatitis, nephritis, immune-related endocrinopathies
Ipilimumab	• Metastatic melanoma, renal cell carcinoma (in combination therapy)	Advanced melanoma; frequently used with nivolumab in combination regimens	Infusion monitoring; higher immune toxicity risk	• IV infusion; 3 mg/kg every 3 weeks for 4 doses	Severe immune-related adverse reactions including colitis and hepatitis
Atezolizumab	• NSCLC, urothelial carcinoma, triple-negative breast cancer	PD-L1 expressing metastatic tumors; first-line or subsequent therapy	Infusion center monitoring	• IV infusion; 840 mg every 2 weeks OR 1200 mg every 3 weeks OR 1680 mg every 4 weeks	Pneumonitis, immune hepatitis, endocrine disorders
Durvalumab	• NSCLC, small cell lung cancer	Consolidation therapy after chemoradiation for Stage III NSCLC	Infusion monitoring	• IV infusion; 10 mg/kg every 2 weeks OR 1500 mg every 4 weeks	Pneumonitis, thyroid disorders, immune toxicities
Avelumab	• Merkel cell carcinoma, urothelial carcinoma	Metastatic disease; maintenance therapy after platinum chemotherapy	Infusion monitoring	• IV infusion; 800 mg every 2 weeks	Infusion reactions, immune-mediated toxicity

Cytokine Therapy

Cytokines are **immune-modulating proteins that enhance immune system activity against tumors** by stimulating T-cells, NK cells and macrophages.

Common cytokines used in cancer immunotherapy:

- Interleukin-2 (IL-2)
- Interferon-alpha

Administration

- **Intravenous infusion or subcutaneous injection**
- High-dose therapy often requires **inpatient monitoring due to toxicity**

Commonly Used for:

- Metastatic melanoma
- Metastatic renal cell carcinoma
- Hairy cell leukemia
- Chronic myelogenous leukemia

Common Limitations

- High toxicity - Severe systemic effects including capillary leak syndrome and hypotension
- Hospitalization requirement - High-dose IL-2 therapy often requires ICU-level monitoring
- Lower efficacy compared to newer immunotherapies - Many cytokine therapies are being replaced by checkpoint inhibitors
- Severe side effects - Flu-like symptoms, fatigue, depression, organ dysfunction
- Narrow therapeutic window - Small difference between effective dose and toxic dose

Globally Approved Treatments

Brand Name	Generic Name	Target	Approved Indications	FDA Approval
Proleukin	Aldesleukin	IL-2 receptor	Metastatic melanoma, renal cell carcinoma	Approved
Roferon-A	Interferon alfa-2a	Immune modulation	Hairy cell leukemia, melanoma	Approved
Intron A	Interferon alfa-2b	Immune modulation	Melanoma, leukemia	Approved

Treatments available in India and CDSCO Approval

Brand Name	Generic Name	Target	Approved Indications	CDSCO Approval
Proleukin	Aldesleukin	IL-2	Renal cell carcinoma	Approved
Intron A	Interferon alfa-2b	Cytokine	Melanoma, leukemia	Approved
Pegasys	Peginterferon alfa-2a	Cytokine	Leukemia	Approved

Name of Treatment	Conditions Treated	Indication for Use (specific condition, stage, sequence)	Indication for Hospitalization / Monitoring	Dosage Form and Typical Duration	Principal Adverse Reactions / Safety Notes
Aldesleukin (IL-2)	• Metastatic renal cell carcinoma, metastatic melanoma	Advanced metastatic disease in selected patients with good performance status	Often requires inpatient hospitalization due to severe toxicity	• IV infusion; 600,000 IU/kg every 8 hours for up to 14 doses per cycle	• Capillary leak syndrome, hypotension, organ toxicity
Interferon alfa-2a	• Hairy cell leukemia, melanoma	Adjuvant therapy in melanoma or hematologic malignancies	Usually outpatient with close monitoring	• Subcutaneous injection; dose varies (e.g., 3–9 million IU multiple times weekly)	Flu-like symptoms, fatigue, depression
Interferon alfa-2b	• Melanoma, leukemia	Adjuvant therapy for high-risk melanoma	Outpatient monitoring	• SC or IM injection; high-dose induction followed by maintenance therapy	Cytopenias, fatigue, psychiatric effects

Monoclonal Antibodies (Cancer Targeting)

Monoclonal antibodies are **laboratory-engineered antibodies designed to bind specific tumor antigens**, resulting in:

- direct tumor cell killing
- immune-mediated cytotoxicity
- blocking tumor growth pathways

Administration

- **Intravenous infusion**
- Cycles every **1–4 weeks**

Widely used for:

- Breast cancer
- Lymphomas
- Leukemia
- Colorectal cancer
- Gastric cancer

Common Limitations

- Biomarker requirement - Only effective when target antigen is present (HER2, CD20, EGFR, etc.)
- Resistance development - Tumors may develop mutations leading to treatment resistance
- Infusion reactions - Risk of severe allergic or infusion reactions
- Organ toxicity - Some drugs cause cardiotoxicity or bleeding risk
- Repeated infusion cycles - Long-term therapy often needed

Globally Approved Treatments

Brand Name	Generic Name	Target Antigen	Approved Indications	FDA Approval
Herceptin	Trastuzumab	HER2	HER2-positive breast cancer	Approved
Rituxan	Rituximab	CD20	Non-Hodgkin lymphoma	Approved
Avastin	Bevacizumab	VEGF	Colorectal, lung cancer	Approved
Erbitux	Cetuximab	EGFR	Colorectal cancer	Approved
Pacdev	Enfortumab vedotin-ejfv	Nectin-4	Bladder Cancer (urothelial cancer)	Approved

Treatments available in India and CDSCO Approval

Brand Name	Generic Name	Target	Approved Indications	CDSCO Approval
Herceptin	Trastuzumab	HER2	Breast cancer	Approved
MabThera	Rituximab	CD20	Non-Hodgkin lymphoma	Approved
Avastin	Bevacizumab	VEGF	Colorectal cancer	Approved
Erbitux	Cetuximab	EGFR	Colorectal cancer	Approved
Pacdev	Enfortumab vedotin-ejfv	Nectin-4	Bladder Cancer (urothelial cancer)	Approved

Name of Treatment	Conditions Treated	Indication for Use (specific condition, stage, sequence)	Indication for Hospitalization / Monitoring	Dosage Form and Typical Duration	Principal Adverse Reactions / Safety Notes
Trastuzumab	• HER2-positive breast cancer, gastric cancer	HER2 overexpression confirmed by diagnostic testing; adjuvant or metastatic therapy	Infusion monitoring; cardiac monitoring required	• IV infusion; loading dose 8 mg/kg then 6 mg/kg every 3 weeks	Cardiotoxicity, infusion reactions
Rituximab	• Non-Hodgkin lymphoma, chronic lymphocytic leukemia	CD20-positive B-cell malignancies	Infusion monitoring due to infusion reactions	• IV infusion; 375 mg/m² weekly or per chemotherapy cycle	Infusion reactions, infections
Bevacizumab	• Colorectal cancer, lung cancer, renal cell carcinoma	Metastatic tumors requiring VEGF inhibition	Infusion monitoring	• IV infusion; 5–15 mg/kg every 2–3 weeks depending on regimen	Hypertension, bleeding, thrombosis
Cetuximab	• Colorectal cancer, head and neck cancers	EGFR-expressing tumors with RAS wild-type status	Infusion monitoring, antihistamine premedication	• IV infusion; 400 mg/m² loading dose then 250 mg/m² weekly or 500 mg/m² every 2 weeks	Acneiform rash, infusion reactions
Enfortumab vedotin-ejfv	• Bladder Cancer (urothelial carcinoma)	Patients treated with platinum-chemotherapy and/or PD-1/PD-L1 inhibitor Used as first line of treatment in combination with Pembrolizumab	Infusion center monitoring required	• IV Infusion; 28 day cycle; 1.25mg/kg (max 125mg) • 21 Day cycle if used in combination with 200 mg pembrolizumab every 3 weeks (400mg if every 6 weeks)	Rash, Neuropathy, severe skin reactions, fatigue, hyperglycemia

Cancer Vaccines

Cancer vaccines **stimulate the immune system to recognize tumor-specific antigens and attack cancer cells**.

Types:

- Therapeutic vaccines (for existing cancer)
- Preventive vaccines (e.g., HPV)

Administration

- Intravenous infusion or intradermal injection
- Often multiple doses over several weeks

Used for:

- Prostate cancer
- Prevention of HPV-related cancers
- Prevention of hepatitis-B-related liver cancer

Common Limitations

- Highly specific indications - For example Sipuleucel-T is limited to metastatic prostate cancer
- Delayed clinical response - Immune activation may take month
- Preventive vs therapeutic limitations - Some vaccines prevent infection-related cancers but do not treat existing cancers
- High cost - Autologous cell therapies are expensive

Globally Approved Treatments

Brand Name	Generic Name	Target Antigen	Approved Indications	FDA Approval
Provenge	Sipuleucel-T	PAP antigen	Metastatic prostate cancer	2010
Gardasil	HPV vaccine	HPV antigens	Cervical cancer prevention	2006
Cervarix	HPV vaccine	HPV antigens	Cervical cancer prevention	2009

Treatments available in India and CDSCO Approval

Brand Name	Generic Name	Target	Approved Indications	CDSCO Approval
Provenge	Sipuleucel-T	PAP	Prostate cancer	Limited availability
Gardasil	HPV vaccine	HPV	Cervical cancer prevention	Approved
Cervarix	HPV vaccine	HPV	Cervical cancer prevention	Approved

Name of Treatment	Conditions Treated	Indication for Use (specific condition, stage, sequence)	Indication for Hospitalization / Monitoring	Dosage Form and Typical Duration	Principal Adverse Reactions / Safety Notes
Sipuleucel-T	• Metastatic castration-resistant prostate cancer	Asymptomatic or minimally symptomatic metastatic disease	Infusion monitoring required	• IV infusion; 3 doses given at approximately 2-week intervals	Fever, chills, infusion reactions
HPV Vaccine (Gardasil)	• Prevention of cervical and HPV-related cancers	Preventive immunization before HPV exposure	Outpatient vaccination	• Intramuscular injection; 2-dose or 3-dose schedule depending on age	Injection site pain, fever
HPV Vaccine (Cervarix)	• Prevention of cervical cancer	Prevention of HPV-16/18 infection	Outpatient vaccination	• Intramuscular injection; 3-dose schedule	Local injection reactions

Contraindications (Absolute and Relative) – Common Across Different Theapies

Therapy / Treatment	Conditions Treated	Absolute Contraindications	Relative Contraindications
Pembrolizumab / Nivolumab	Multiple solid tumors	Severe hypersensitivity to drug components	Active autoimmune disease, organ transplant
Ipilimumab	Melanoma	Severe immune toxicity history	Chronic inflammatory disorders
Aldesleukin	RCC, melanoma	Severe cardiac or pulmonary disease	Renal impairment
Interferons	Leukemia, melanoma	Severe psychiatric illness	Autoimmune disease
Trastuzumab	HER2 cancers	Severe cardiomyopathy	Pregnancy
Rituximab	Lymphoma	Severe hypersensitivity	Active hepatitis B infection
Bevacizumab	Solid tumors	Recent major surgery, severe bleeding risk	Uncontrolled hypertension
Cetuximab	CRC, head & neck cancer	Severe hypersensitivity reactions	Electrolyte abnormalities
Sipuleucel-T	Prostate cancer	Severe hypersensitivity	Immunosuppression

Robotic Surgeries: An Overview

What is Robotic Surgery?
Robotic surgery is a form of minimally invasive surgery where surgeons use a computer-controlled robotic system to perform complex procedures with enhanced precision, flexibility, and control. These systems consist of robotic arms controlled from a console and offer benefits such as smaller incisions, shorter hospital stays, and reduced recovery times.

Conditions Treated	
Urology	Prostate cancer, kidney cancer, bladder cancer, adrenalectomy, nephrectomy, partial nephrectomy, pyeloplasty, ureteral reimplantation, ureteroureterostomy
Gynecology	Hysterectomy (benign & malignant), myomectomy, fibroids, pelvic prolapse, endometriosis, excessive bleeding, ovarian cystectomy, adnexectomy
General Surgery	Hernias, cholecystectomy, bariatric procedures (gastric bypass/sleeve), hiatal hernia repair, complex abdominal wall reconstruction, achalasia, gallbladder disease, diverticular disease, complex gallbladder disease
Colorectal	Colon/rectal cancer, IBS, rectal prolapse, transanal minimally invasive surgery (TAMIS), diverticular disease, colectomy (total/partial/segmental)
Thoracic/Cardiac	Lung/esophageal/thymic cancers, mediastinal tumors, thymectomy for myasthenia gravis, diaphragm plication, fundoplication, Heller myotomy, CABG, minimally invasive lung transplant
Head & Neck / ENT	Tonsil/base tongue/pharyngeal/laryngeal cancers, sleep apnea (TORS), chronic tonsillitis, parapharyngeal tumors, thyroidectomy (transaxillary), cochlear implantation
Hepatobiliary / Pancreatic	Liver resections (segmentectomy, lobectomy), pancreaticoduodenectomy, distal pancreatectomy, central pancreatectomy, donor hepatectomy
Orthopedic / Spine	Total hip/knee arthroplasty (ROBODOC, Acrobot, Mazor X), pedicle screw placement
Pediatric urology	Pyeloplasty, pyeloureterostomy, nephrectomy in children

Developers and Machine Suppliers

System	Developer	Application areas	Notable features
da Vinci Surgical System	Intuitive Surgical	Urology (prostatectomy), gynecology (hysterectomy), general & colorectal, thoracic, ENT, HPB	Mature multi-arm platform, broad instrument ecosystem, 3-D HD vision, wristed instruments, largest installed base globally.
Versius	CMR Surgical	General surgery (cholecystectomy, colorectal), gynecology, urology	Modular bedside arms, compact footprint designed for flexible deployment; marketed for MIS soft-tissue surgery.
Dexter (DEXTER)	Distalmotion	Inguinal hernia, general laparoscopic procedures	Bedside mobile robot aimed at outpatient/ambulatory MIS

System	Developer	Application areas	Notable features
Senhance	Asensus Surgical (formerly TransEnterix)	Laparoscopic general surgery, gynecology, urology	Laparoscopic-style with haptic (force) feedback, eye-tracking camera control; reusable instruments to reduce per-case cost.
MIRA (mini-RAS)	Virtual Incision	Colectomy mobilization (colorectal)	Miniaturized intracavitary robot to reduce port trauma
Maestro	Moon Surgical	General laparoscopy, bariatric, gynecology, urology (component clearances)	AI-enabled assistance (ScoPilot), connectivity modules; commercial 510(k)s for components and connectivity.
Ottava	Johnson & Johnson MedTech	Intended: complex upper-GI, bariatric (investigational)	Modular multi-arm platform; IDE / investigational program in US (clinical cases under IDE).
SSi Mantra / SSI Mantra	SS Innovations (India)	Cardiac surgery, general surgery, telesurgery / tele-proctoring	Indigenous Indian system with CDSCO permissions for telesurgery/teleproctoring; emphasizes remote connectivity with local backup.
ROSA (ROSA One, ROSA Brain/Spine/Knee/Hip)	Medtech / Zimmer Biomet	Neurosurgery (DBS, tumor resection), spine instrumentation, knee/hip arthroplasty	Navigation + robotic positioning across brain, spine and ortho
Ion Endoluminal System (Ion)	Intuitive Surgical	Peripheral bronchoscopy, biopsy of peripheral lung nodules	Articulating catheter for peripheral airway access
MONARCH Platform	Ethicon / Johnson & Johnson (Auris historically)	Robotic bronchoscopy & endoscopic airway access; endourology extensions	Flexible robotic bronchoscopy platform for diagnostic and therapeutic access to airways
CorPath / Corindus (CorPath GRX)	Corindus / Siemens Healthineers	Percutaneous coronary intervention (PCI), peripheral vascular interventions	Robotic catheter-control cockpit for cath lab; reduces operator radiation exposure & enables fine movements.
Hugo RAS	Medtronic	Intended: urology, general MIS	Multi-arm modular design
MAKO	Stryker	Orthopedic arthroplasty: knee, hip, shoulder	Robotic-arm assisted joint replacement with CT planning and haptic guidance
Mazor / SpineAssist / Renaissance (Mazor then Medtronic)	Mazor Robotics (acquired by Medtronic)	Spine navigation & guidance (pedicle screw placement)	Early spine robotic guidance

OT Protocols for Robotic Surgery

Robotic surgeries follow strict pre-operative, intra-operative, and post-operative protocols:

- **Pre-Operative**:
  - Patient selection based on disease stage, comorbidities
  - Pre-op labs, imaging, anesthesia clearance
- **Intra-Operative**:
  - Docking the robot after port placement
  - Surgeon operates via console
  - Laparoscopic assistants monitor trocars and instruments
- **Post-Operative**:
  - Monitoring for infection, bleeding
  - Discharge typically in 24–72 hours
  - ERAS (Enhanced Recovery After Surgery) protocols

Approval Status Globally and in India

System	FDA Approval (Type & Year)	CDSCO / India Status
da Vinci	510(k) & PMA — Initial 2000; multiple updates (latest 2024)	Widely used; registered via distributor/importer (Intuitive India)
Versius	De Novo — 2024 (cholecystectomy)	Marketed in India since 2019; distributor-based clearance
Dexter	De Novo — 2024; 510(k) — 2025	No public CDSCO record; India presence not confirmed
Senhance	510(k) — 2017; updates 2023, 2024	Installed globally; India registration via distributor channels
MIRA	De Novo — 2024 (colectomy)	❌
Maestro	510(k) — 2023, 2024, 2025	❌
Ottava	IDE — 2024 (investigational only)	❌
SSi Mantra	⚠️	CDSCO approval (telesurgery/teleproctoring) — 2024
ROSA	510(k) — 2015–2019 (brain/spine); 2019 (knee)	Used globally; India presence via local distributors
Ion	510(k) — 2019 (bronchoscopy)	❌
MONARCH	510(k) — 2018 (bronchoscopy); 2022 (urology)	❌
CorPath GRX	510(k) — 2016, 2018	Used globally; India presence via Siemens distributor
Hugo RAS	CE Mark; FDA submission ongoing (2025)	Presence in some markets
MAKO	510(k) — 2010+, knee (2015), newer 2024	Widely used in India; registered via Stryker India
Mazor	510(k) — 2004+ (spine); ongoing updates	Used globally; present in India via Medtronic

Advantages and Limitations of Robotic Surgeries

Advantages:

- Reduced blood loss and transfusion risk
- Lower conversion rates to open surgery
- Slightly shorter hospital stays
- Improved ergonomics and precision for surgeons
- Better outcomes in complex anatomical zones (e.g., deep pelvis, obesity)

Limitations

- **Longer operative times** (On an average 60 minutes extra)
- **Higher equipment and OR costs**
- **Learning curve**: Full proficiency may require minimum 60 cases for prostatectomy and 250 & more for being considered an expert
- **Limited long-term benefit** in many routine procedures (equivalent outcomes but higher cost)

Outcomes for few Surgery Types (Robotic vs Conventional)

- **Endometrial Cancer**

Study Conducted by: Department of Gynecology and Obstetrics of Tampere University Hospital, Finland between 2010 and 2013 with 101 patients

Key Findings:

- **Overall Survival**: Slightly favored robotic (Hazard Ratio 0.39; 95% Confidence Interval)
- **No Difference:** The incidence of lymphocele, lymphedema, or other long-term complications did not differ between the groups
- **Incidence for Hernia:** Trocar site hernia developed more often for the robotic-assisted group compared to the conventional laparoscopy group 18.2% vs 4.1%

Rectal Cancer / Colorectal Surgery

- A DARE meta-analysis (1,493 patients) showed that robotic surgery reduced:
  - **Blood loss**: ~18 mL less
  - **Hospital stay**: ~0.5 day shorter
  - **Conversion to open**: 3% lower
  - **Operative time**: ~35 minutes longer

- For colon cancer, a 2020–2024 meta-review found robotic surgery yielded:
  - Shorter stays and higher lymph node yield (better oncologic thoroughness)
  - Longer operative time; similar complication rates

Hysterectomy

- Cureus 2021 review: Robotic and conventional laparoscopy had similar patient outcomes; robotic had higher costs but may benefit specific subsets (e.g. obese patients, large uteri > 750 g)

Colorectal Resection (Rectal Cancer)

- PubMed 2018 meta-analysis (19,731 patients):
- Lower conversion to open (OR 0.40)
- Shorter hospital stay by 0.77 days
- Less blood loss by ~18 mL
- Longer operative time (~38 min)

Total Hip Arthroplasty (Orthopedics)

- EFORT Open Rev meta-analyses:
- Improved radiographic accuracy, fewer intra-op complications
- Longer operation time, possible increases in heterotopic ossification, dislocation, and revisions
- No differences in functional or clinical scores

Robotic Surgeries: Clinical Overview

Procedure & System	Conditions Treated	Indication (What & When It's Used)	Hospitalization / Monitoring	Procedure Form & Duration
Radical Prostatectomy (da Vinci)	Prostate cancer	Used when cancer is limited to prostate and needs complete removal	2–3 days; catheter in place after surgery	Robotic keyhole surgery; 2–4 hours
Hysterectomy (da Vinci / Versius)	Fibroids, endometriosis, early uterine or cervical cancer	Used when uterus is diseased or cancerous	2–3 days; monitor bleeding, urine	Robotic uterus removal; 2–3 hours
Myomectomy (da Vinci)	Uterine fibroids	When fibroids cause heavy bleeding or infertility	2 days; watch for bleeding	Robotic fibroid removal; 2–3 hours
Colorectal Resection (da Vinci / Versius)	Colon or rectal cancer, diverticulitis	When part of bowel is cancerous or badly damaged	3–5 days; bowel recovery checks	Robotic bowel removal; 3–4 hours
Cholecystectomy (Versius / Senhance)	Gallstones, gallbladder infection	When gallstones cause pain or infection	1–2 days; watch for bile leak	Robotic gallbladder removal; 1–2 hours
Hernia Repair (Versius / Senhance / Dexter)	Inguinal or ventral hernia	When hernia causes pain or risk of obstruction	1–2 days; wound checks	Robotic mesh repair; 1–2 hours
Robotic Bronchoscopy (Ion / Monarch)	Lung nodules, suspected lung cancer	To take biopsy from hard-to-reach lung spots	Daycare; watch for lung collapse	Robotic scope biopsy; 1–1.5 hours
Lobectomy (da Vinci / Hugo RAS)	Early-stage lung cancer	To remove cancerous lung lobe	4–5 days; chest drain monitoring	Robotic lung resection; 3–4 hours
Thymectomy (da Vinci)	Thymoma, myasthenia gravis	When thymus gland needs removal	3–4 days; breathing checks	Robotic gland removal; 2–3 hours
Total Knee Replacement (MAKO)	End-stage knee arthritis	When pain and joint damage are severe	3–5 days; physiotherapy needed	Robotic joint replacement; 1–2 hours
Total Hip Replacement (MAKO)	Hip arthritis, hip fracture	When hip joint is severely damaged	3–5 days; rehab after surgery	Robotic joint replacement; 1–2 hours
Partial Knee Replacement (MAKO)	Localized knee arthritis	When only one knee compartment is damaged	2–3 days; physio	Robotic partial joint replacement; 1–1.5 hours
Deep Brain Stimulation (ROSA)	Parkinson's, tremor	When medicines don't control tremors	4–5 days; brain checks	Robotic brain electrode placement; 3–6 hours
Spine Surgery (ROSA / Mazor)	Spine deformities, tumors, instability	When spine is unstable or compressing nerves	3–7 days; neuro checks	Robotic screw placement; 3–6 hours
Robotic PCI (CorPath GRX)	Blocked heart arteries	When arteries are blocked and need stenting	Same-day or 1 day; ECG monitoring	Robotic heart stent; 1–2 hours
Robotic Cardiac Surgery (SSi Mantra)	Valve or bypass heart surgery	When valve repair or bypass is needed	5–7 days; ICU stay	Robotic heart surgery; 4–6 hours
Appendectomy (Hugo RAS / Dexter)	Appendicitis	When appendix is infected	2–3 days; infection watch	Robotic appendix removal; 1–2 hours
Colectomy (Hugo RAS / da Vinci)	Colon cancer, IBD	When large part of colon is diseased	4–6 days; bowel recovery checks	Robotic colon removal; 3–5 hours
Robotic Low Anterior Resection / TME (da Vinci / Hugo RAS)	Lower rectal cancer (CA rectum – lower 3rd)	Used when tumor is in lower rectum requiring precise dissection in narrow pelvis; preferred in difficult anatomy (male pelvis, obesity)	3–5 days; bowel recovery, anastomotic leak monitoring	Robotic rectal resection; 3–5 hours
Robotic Partial Nephrectomy (da Vinci)	Localized kidney tumor	Used when tumor is small and kidney-sparing surgery is feasible; preferred to preserve renal function	2–4 days; renal function monitoring, bleeding	Robotic kidney tumor excision; 2–4 hours

Procedure & System	Conditions Treated	Indication (What & When It's Used)	Hospitalization / Monitoring	Procedure Form & Duration
Robotic Ventral Mesh Rectopexy (da Vinci)	Rectal prolapse	Used in full-thickness rectal prolapse where abdominal approach is indicated	2–3 days; bowel function monitoring	Robotic rectal fixation with mesh; 2–3 hours
Robotic Abdominoperineal Resection (da Vinci / Hugo RAS)	Anal canal cancer (salvage cases)	Used only when cancer persists/recurs after chemoradiotherapy; not first-line treatment	4–7 days; wound care, stoma management	Robotic rectum + anus removal; 4–6 hours

Procedure & System	Conditions Treated	Absolute Contraindications (Stop)	Relative Contraindications(Caution)
Radical Prostatectomy (da Vinci)	Prostate cancer	Severe heart/lung disease, bleeding disorder, severe pelvic scarring	Older age, obesity, prior pelvic surgery
Hysterectomy / Myomectomy (da Vinci)	Fibroids, cancers	Severe heart/lung issues, active pelvic infection, bleeding disorder	Obesity, prior abdominal surgeries
Colorectal Resection (da Vinci / Versius)	Colon & rectal disease	Uncontrolled sepsis, severe heart/lung disease, bleeding disorder	Frailty, obesity, adhesions
Cholecystectomy (Versius / Senhance)	Gallstones	Uncontrolled infection, bleeding disorder, severe heart/lung disease	Liver cirrhosis, obesity, adhesions
Hernia Repair (Versius / Dexter)	Hernias	Severe heart/lung instability, bleeding disorder	Chronic cough, frailty, obesity
Robotic Bronchoscopy (Ion / Monarch)	Lung nodules	Severe breathing difficulty, bleeding disorder, low oxygen	Asthma/COPD flare, older age
Lobectomy (da Vinci / Hugo RAS)	Lung cancer	Severe lung disease, uncontrolled infection, bleeding disorder	Older age, frailty, prior chest surgery
Thymectomy (da Vinci)	Thymoma	Severe heart/lung issues, uncontrolled infection	Older age, prior chest surgery
Total Knee / Hip Replacement (MAKO)	Arthritis	Active infection, severe osteoporosis, allergy to implant	Obesity, diabetes, weak heart
Deep Brain Stimulation (ROSA)	Parkinson's	Active infection, bleeding disorder, unstable illness	Frailty, dementia, older age
Spine Surgery (ROSA / Mazor)	Spine deformity/tumor	Active infection, bleeding disorder, severe heart/lung disease	Osteoporosis, obesity, prior spine hardware
Robotic PCI (CorPath GRX)	Heart blockages	No arterial access, active bleeding	Kidney problems, dye allergy, weak heart
Robotic Cardiac Surgery (SSi Mantra)	Valve/bypass	Severe bleeding disorder, unstable heart failure	Long surgery risk, prior chest surgery
Appendectomy / Colectomy (Hugo / da Vinci)	Appendix, colon disease	Uncontrolled sepsis, bleeding disorder, severe heart/lung disease	Obesity, adhesions, frailty
Robotic Low Anterior Resection / TME (da Vinci / Hugo RAS)	CA Rectum (Lower 3rd)	Uncontrolled sepsis; inability to tolerate general anesthesia; uncorrected coagulopathy; locally unresectable disease invading critical structures	Narrow pelvis with bulky tumor; prior pelvic radiation; obesity; extensive adhesions; locally advanced T4 disease
Robotic Partial Nephrectomy (da Vinci)	Localized kidney tumor	Unfit for anesthesia; uncontrolled bleeding disorder; tumor not amenable to nephron-sparing (large/complex mass requiring radical nephrectomy)	Complex hilar tumors; solitary kidney with high surgical risk; obesity; prior renal surgery; poor baseline renal function
Robotic Ventral Mesh Rectopexy (da Vinci)	Rectal prolapse	Active pelvic infection; unfit for anesthesia; generalized peritonitis	Severe constipation-dominant disease; prior extensive pelvic surgery; adhesions; obesity
Robotic Abdominoperineal Resection (da Vinci / Hugo RAS)	CA Anal Canal (salvage cases)	Uncontrolled sepsis; unfit for major surgery; unresectable/metastatic disease where surgery not indicated	Prior chemoradiotherapy (fibrosis); poor wound healing risk; malnutrition; obesity; advanced local invasion

Notes on contraindications (general): most robotic procedures share common absolute contraindications — inability to tolerate general anesthesia; uncontrolled sepsis; uncorrected coagulopathy; severe cardiopulmonary compromise that precludes pneumoperitoneum and/or required positioning. Pregnancy is an absolute contraindication for elective intra-abdominal/minimally invasive procedures in most protocols.

Position Statement (Sample)

Procedure / Condition	Robotic Technique	Surgical System	Next-Best Alternative	Which Is Better (Clinical / Economic)	QALY Gain	Evidence Summary	Suggested Claims Position
Prostate Cancer	Robotic-Assisted Radical Prostatectomy	da Vinci Surgical System / Hugo Robotic-Assisted Surgery System	Laparoscopic Radical Prostatectomy / Open Radical Prostatectomy	Robotic better clinically and economically in high-volume centres	+0.12–0.24 QALY	Better urinary continence outcomes and reduced hospital stay	To Cover Robotic
Total Knee Arthroplasty	Robotic-Arm Assisted Total Knee Arthroplasty	MAKO Robotic System / ROSA Robotic System	Conventional Manual Total Knee Arthroplasty	Similar clinical outcomes; robotic better only at high-volume centres	0.03–0.26 QALY	Cost-effective only when procedure volume is high	To Pay for Conventional
Hip Arthroplasty	Robotic Total Hip Arthroplasty	MAKO Robotic System / ROSA Robotic System	Conventional Total Hip Arthroplasty	Comparable clinical outcomes; robotic adds cost	Limited QALY data; volume-dependent	Improved implant placement but uncertain long-term benefit	Conventional Total Hip Arthroplasty To Be Paid
Hysterectomy	Robotic Assisted Laparoscopic Surgery	da Vinci Surgical System / Hugo Robotic-Assisted Surgery System	Conventional Laparoscopic Hysterectomy / Open Hysterectomy	Conventional approach better economically	≈ 0 QALY	No measurable benefit except in complex oncological cases	Conventional To Be Paid
Cholecystectomy	Robotic Cholecystectomy	da Vinci Surgical System / Hugo Robotic-Assisted Surgery System	Laparoscopic Cholecystectomy	Conventional approach better clinically and economically	No QALY gain; approximately 2.5× cost of Laparoscopic Cholecystectomy	Higher cost and no advantage	Conventional / Laparoscopic To Be Paid
Colonic Malignancy	Robotic Colectomy / Total Mesorectal Excision	da Vinci Surgical System / Hugo Robotic-Assisted Surgery System	Laparoscopic Colectomy / Open Colectomy	Clinically slightly better; economically inferior	Small QALY gain	Lower conversion rates and reduced length of stay in some centres	Conventional To Be Paid
Cataract	Manual Small-Incision Cataract Surgery / Phacoemulsification / Femtosecond Laser-Assisted Cataract Surgery	Phacoemulsification systems (Alcon, Johnson & Johnson); Femtosecond platforms (LenSx, Catalys, Z8)	Manual Small-Incision Cataract Surgery (default) / Phacoemulsification (alternative)	Manual Small-Incision Cataract Surgery better economically; similar clinical outcomes	Manual Small-Incision Cataract Surgery dominant; Phacoemulsification marginal gain	Manual Small-Incision Cataract Surgery most cost-effective	Conventional To Be Paid (Manual Small-Incision Cataract Surgery)
CA Rectum (Lower 3rd)	Robotic Low Anterior Resection / Total Mesorectal Excision	da Vinci Surgical System / Hugo RAS	Laparoscopic TME / Open Surgery	Clinically: Marginal benefit in select cases (lower conversion, better margins); Economically: Higher Cost	~0.01 QALY (short-term QoL only; negligible)	Lower conversion rates, improved CRM, better functional outcomes in some studies; no significant survival difference; higher cost and ICER above threshold	Conditional cover (Robotic restricted to complex pelvis / male / obese patients)
Partial Nephrectomy	Robotic-Assisted Partial Nephrectomy (RAPN)	da Vinci Surgical System	Laparoscopic Partial Nephrectomy / Open Partial Nephrectomy	Clinically: Better perioperative outcomes (less blood loss, shorter LOS); Economically: Higher cost but widely adopted standard	Small QALY gain (Limited Data Available)	Robotic approach associated with reduced complications, ischemia time, and LOS vs open; comparable oncologic outcomes to laparoscopy (widely reported across urology literature)	To Cover Robotic

Procedure / Condition	Robotic Technique	Surgical System	Next-Best Alternative	Which Is Better (Clinical / Economic)	QALY Gain	Evidence Summary	Suggested Claims Position
Rectopexy (Rectal Prolapse)	Robotic Ventral Mesh Rectopexy	da Vinci Surgical System	Laparoscopic Rectopexy / Open Rectopexy	Clinically: Better Comparable outcomes; Economically: Higher Cost	Small QALY gain	Lower recurrence, complications, and functional outcomes vs laparoscopy	Robotic To Be Paid (due to better Clinical evidences)
CA Anal Canal	Robotic Abdominoperineal Resection (APR)	da Vinci Surgical System	Open APR / Laparoscopic APR + Chemo-radiotherapy (standard primary treatment)	Clinically: Only post chemo-radiotherapy; Economically: No justification	No QALY data available. Is only done post Chemo-radiotherapy	Standard of care is chemo-radiotherapy; surgery reserved for salvage;	Robotic To Be Paid

Please Note: Cataract surgery **does not have a robotic surgical option**. The commonly used techniques—Manual Small-Incision Cataract Surgery (MSICS), Phacoemulsification, and Femtosecond Laser-Assisted Cataract Surgery—are **manual or laser-assisted**, not robotic. Cataract surgery is included in the table **only for comparative assessment**, not as a robotic procedure.

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