Place of Service Policy: Oncology Infusion Site of Care Management

Executive Sponsor: Chief Medical Officer

Issuing Department: Health Services Management (HSM) – Clinical Management

Gate Keeper: Director, Clinical Management

COMPLIANCE STATEMENT:

Enforcement: All members of the workforce are responsible for compliance with this policy. Failure to abide by the requirements of this policy may result in corrective action, up to and including termination. Workforce members are responsible for reporting any observed violations of this policy.

Review Schedule: This policy will be reviewed and updated as necessary and no less than every two years.

Monitoring and Auditing: The Issuing/Collaborating Department(s) is responsible for monitoring compliance with this policy.

Documentation: Documentation related to this policy must be maintained for a minimum of 10 years.

Applies to:

☒ **SummaCare APEX**	☒ **Summa Insurance Company**
☒ **Summa Management Service Organization (SMSO)**	
☒ **Commercial Groups**	☐ **Medicare**
☐ **Medicare Supplemental**	☒ **On Exchange**
☒ **Off Exchange**	☒ **Self-Funded**

1.0 Purpose:

This policy establishes the criteria and guidelines governing the appropriate site of care for oncology infusion therapy administered to SummaCare members. The primary objective is to ensure that covered infusion drugs are delivered in the most clinically appropriate and cost-effective setting — specifically, physician office or home-based

settings (Place of Service 11 or 12) — while preserving clear, auditable pathways for members who have documented clinical need for hospital-based administration.

This policy is intended for use by EviCore, SummaCare's designated utilization management partner, as the governing framework for reviewing, approving, and redirecting prior authorization requests for oncology infusion therapy. All determinations must be consistent with these criteria and documented in the authorization record.

2.0 Scope:

This policy applies to all prior authorization requests submitted to EviCore for oncology infusion drugs on the SummaCare Site of Care Redirect Drug List (Attachment A), across all SummaCare commercial lines of business. It applies to all participating and non-participating providers submitting requests for covered members, regardless of the provider's primary practice setting.

This policy does not apply to emergency department encounters (POS 23), inpatient hospital admissions (POS 21), or drugs administered exclusively in an inpatient setting for reasons unrelated to site of care optimization.

3.0 Policy Statement:

SummaCare requires that oncology infusion drugs on the Site of Care Redirect Drug List be administered in a Preferred Setting (POS 11 or POS 12) unless the member's clinical condition satisfies one or more of the defined Non-Preferred Setting exceptions set forth in Section 5.

Hospital outpatient department settings (POS 19 and POS 22) are designated Non-Preferred Sites of Care. Authorization at a Non-Preferred Site is not automatic and requires affirmative, individualized clinical documentation meeting the specific exception criteria herein. Broad clinical language, templated attestations, provider preference, or administrative convenience do not constitute grounds for Non-Preferred Site authorization.

EviCore is authorized and directed to enforce this policy at the point of prior authorization. SummaCare reserves the right to conduct retrospective audits of all Non-Preferred Site authorizations and to pursue corrective action where criteria were not met.

4.0 Definitions:

Term	Definition
Preferred Setting	A physician office (POS 11), stand-alone infusion center affiliated with a physician practice (POS 11), or member's home (POS 12). Required default for all drugs subject to this policy.
Non-Preferred Setting	An on-campus hospital outpatient department (POS 22) or off-campus hospital outpatient department (POS 19). Requires documented clinical exception.
Site of Care Redirect Drug List	See Attachment A for the list of drugs to be managed by eviCore's Point of Service program.

Term	Definition
Documentation of Record	Contemporaneous clinical notes, lab results, or medical records from the treating provider form the basis for a Non-Preferred Site exception. Retrospective documentation added after an audit inquiry is insufficient.
Treating Physician	The licensed physician or advanced practice provider responsible for the member's oncology care who submits or supervises the prior authorization request.

5.1 Site of Care Criteria

5.2 Preferred Setting Authorization (POS 11 or POS 12)

Authorization for a Preferred Setting shall be approved when all of the following are met:

- The drug is on the Site of Care Redirect Drug List.
- Medical necessity for the drug is established.
- The provider has confirmed ability to administer the drug in a Preferred Setting or has agreed to coordinate care to a Preferred Setting provider.

No site-of-care exception documentation is required for Preferred Setting authorization.

5.3 Non-Preferred Setting Authorization (POS 19 or POS 22) — Exception Criteria

Authorization at a Non-Preferred Setting requires that **ALL** threshold conditions in 5.2.1 are satisfied **AND** that at least one clinical exception in 5.2.2 is documented.

5.2.1 Threshold Conditions (All Must Be Met)

1. Medical necessity for the requested drug is established.
2. The facility is a licensed hospital outpatient department under POS 19 or POS 22.
3. The treating physician has submitted a **written attestation** — specific to this member's current clinical status — that the member's condition requires a higher level of care than a Preferred Setting can provide. Templated or pre-populated attestations are not acceptable.
4. The treating physician has confirmed in writing that the Non-Preferred Setting is required for **this drug and this member**, not merely that the hospital is the physician's preferred practice location.

5.2.2 Clinical Exception Criteria (At Least One Required with Supporting Documentation)

EXCEPTION A — Severe Adverse Drug Reaction or Anaphylaxis History

Applies to: Initiation of a new drug or drug class only.

Criteria: The member has a documented history of severe adverse drug reaction (Grade 3 or higher per CTCAE) or anaphylaxis to a prior drug in the same class or with a closely related mechanism of action, requiring emergency medical intervention.

Required Documentation: Clinical notes documenting the prior reaction, severity grade, and treating physician's rationale for requiring hospital-level monitoring at initiation.

Guardrail: This exception applies to **initiation only**. Once the member has received and tolerated at least one full dose of the specific drug being authorized in any setting, this exception is extinguished. All subsequent authorizations must be at a Preferred Setting unless a separate exception applies.

EXCEPTION B — Cytokine Release Syndrome (CRS) Risk

Criteria: The specific drug carries an established CRS risk per FDA labeling or current NCCN Guidelines, **AND** the member's individual clinical profile (e.g., high tumor burden, prior CRS history, advanced disease stage) places them at elevated risk beyond the general patient population.

Required Documentation: Clinical notes identifying the member-specific CRS risk factors. A general statement that the drug class carries CRS risk is insufficient — documentation must address this member's individual profile.

Guardrail: This exception is time-limited to the period of heightened risk (typically early treatment cycles). Authorization length must reflect the documented risk window. Continued authorization under this exception requires fresh documentation at each renewal.

EXCEPTION C — Significant Cardiac or Pulmonary Comorbidity

Criteria: The member has a documented cardiac or pulmonary condition that materially increases adverse reaction risk during infusion and requires monitoring capabilities available only in a hospital outpatient department.

Required Documentation: Objective clinical documentation of the condition (e.g., echocardiogram results, PFTs, specialist consultation note) and a treating physician statement explaining why this specific condition requires hospital-level infusion monitoring for this specific drug.

Guardrail: Stable, well-controlled chronic cardiac or pulmonary conditions that do not create incremental infusion risk do not satisfy this criterion. The condition must be unstable, poorly controlled, or documented by the treating cardiologist or pulmonologist as creating elevated infusion risk.

EXCEPTION D — Unstable Renal Function

Criteria: The member has documented unstable renal function that impairs safe fluid balance management during infusion outside a hospital outpatient setting.

Required Documentation: Current laboratory values (within the prior 30 days) demonstrating unstable or significantly impaired renal function (e.g., acute kidney injury, rapidly declining GFR, dialysis-dependence) and a treating physician statement that hospital-level monitoring is required to manage fluid and electrolyte balance during infusion.

Guardrail: Chronic stable kidney disease — even at advanced stages — does not automatically satisfy this criterion. Instability or acute change must be demonstrated. Authorization under this exception requires updated laboratory values at each renewal.

EXCEPTION E — Difficult or Unstable Vascular Access

Criteria: The member has documented difficult or unstable vascular access that cannot be safely managed in a Preferred Setting, requiring hospital-level nursing or procedural resources.

Required Documentation: Clinical notes documenting prior failed access attempts, implanted access device complications, or other objective vascular access challenges. A statement that the member "has poor veins" without clinical detail is not sufficient.

Guardrail: Members with a functioning, uncomplicated central venous access device (e.g., port-a-cath, PICC line) do not qualify under this exception unless device dysfunction or complication is documented.

EXCEPTION F — Cognitive Conditions or Mental Status Changes

Criteria: The member has a documented cognitive condition or acute mental status change that materially impacts infusion safety in a non-hospital setting and requires the continuous monitoring capability of a hospital outpatient department.

Required Documentation: Clinical notes from the treating physician or specialist documenting the specific condition, its current severity, and the clinical rationale for hospital-level infusion oversight.

Guardrail: Stable cognitive conditions routinely managed in outpatient settings do not qualify. The condition must be acute, unstable, or of a severity requiring continuous observation during infusion.

EXCEPTION G — Documented Clinical Contraindication to Preferred Setting

Narrow exception for clinical circumstances not captured by Exceptions A–F.

Criteria: The member's medical condition is formally documented as clinically contraindicated for any Preferred Setting based on individualized clinical factors.

Required Documentation: A detailed letter from the treating oncologist (not an administrative representative) addressing the specific contraindication, the member's current clinical status, the drug requested, and the clinical rationale precluding Preferred Setting administration.

Guardrail: This is a narrow safety valve for genuinely unusual clinical circumstances. Routine use — particularly for members with stable profiles or members who have previously tolerated the same drug in a Preferred Setting — will trigger heightened audit scrutiny. Provider preference, logistical convenience, and lack of a conveniently located in-network Preferred Setting provider do **not** meet this criterion.

5.3 3 First-Dose Accommodation

For members initiating a new drug for the first time, a single first-dose waiver may be granted at a Non-Preferred Setting under the following conditions:

- The treating physician documents that the first dose warrants heightened monitoring due to the drug's known side effect profile, the member's clinical history, or both.
- The authorization is explicitly limited to **one dose or one infusion encounter**.
- The treating physician commits in writing to transitioning the member to a Preferred Setting for all subsequent maintenance doses, absent a separately documented exception under Section 5.2.

The first-dose waiver does not renew automatically. Members who received a first-dose waiver for the same drug within the preceding 12 months are not eligible for a subsequent first-dose waiver for that drug.

5.4 Third-Party Drug Supply at Non-Preferred Settings

SummaCare retains the right to coordinate direct drug supply from a designated specialty pharmacy or third-party supplier to a Non-Preferred Setting when a clinical exception has been approved. This does not affect the exception criteria or the member's clinical care but ensures appropriate drug pricing and supply chain controls in cases where hospital-based administration is clinically necessary. Providers will be notified in advance.

6. Authorization Process

Step	Action	Requirement
1	Request Received	EviCore receives prior auth request with drug, POS, and member info
2	Drug List Check	Confirm drug is on the Redirect Drug List; if not, standard workflow applies
3	POS Assessment	If POS 11/12 → Step 4. If POS 19/22 → Step 5
4	Preferred Setting Approval	Verify medical necessity → Issue standard authorization

Step	Action	Requirement
5	Non-Preferred Review	Contact provider to submit exception documentation per Section 5.2
6	Documentation Review	Clinical reviewer assesses against exception criteria. Peer-to-peer available
7a	Exception Approved	Issue time-limited authorization (≤30 days). Notify SummaCare via daily report
7b	Exception Not Approved	Redirect to Preferred Setting. Notify SummaCare via daily report
8	SummaCare Coordination	SummaCare contacts providers with Non-Preferred auths to support transition

7. Anti-Abuse and Integrity Provisions

- **Pattern Monitoring:** EviCore shall flag and report to SummaCare any provider or facility pattern suggesting systematic exception documentation without individual clinical differentiation — including identical attestation language submitted for multiple members, or exception rates that are statistical outliers.
- **Retrospective Audit Rights:** SummaCare may audit any Non-Preferred Setting authorization. Audits assess whether supporting documentation existed in the medical record **at the time of the request**. Post-hoc documentation will not be credited.
- **Recoupment:** Where audit finds a Non-Preferred authorization was granted without criteria being met, SummaCare reserves all rights to pursue recoupment of the cost differential between Non-Preferred and Preferred Setting reimbursement.
- **Re-Authorization Requirement:** Non-Preferred authorizations do not carry forward. Each renewal requires fresh documentation confirming the continuing applicability of the exception.
- **No Facility-Level Exceptions:** A provider's primary practice location being a hospital outpatient department does not, by itself, constitute a clinical basis for Non-Preferred Site authorization.
- **Transition Obligation:** When an exception is time-limited, the treating provider is obligated to transition to a Preferred Setting for subsequent authorizations. Failure to document or initiate this transition may result in denial of subsequent Non-Preferred requests for the same member and drug.

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8. Appeals

- **Peer-to-Peer Review:** Treating physician may request peer-to-peer with an EviCore medical director within two business days of determination.
- **Formal Appeal:** Written appeal with additional supporting documentation may be submitted within 30 calendar days.
- **Member Appeals:** Members retain all applicable rights under their benefit plan, state law, and federal law.

Appeals consisting solely of provider preference or general policy disagreement will not be approved. Additional clinical documentation addressing the specific exception criteria is required.

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9. Attachment A — Site of Care Redirect Drug List

(2 drugs and their associated biosimilars are subject to POS Redirection - as maintained by SummaCare P&T Committee)

HCPC	Brand Name	Generic Name	Route
J0897	XGEVA	DENOSUMAB	Subcutaneous

Xgeva and Associated Biosimilars (J0897)

- Denosumab — Xgeva — J0897
- Denosumab-bbdz — Wyost — Q5136
- Denosumab-bmwo — Osenvelt — Q5157
- Denosumab-bnht — Bomyntra — Q5158
- Denosumab-desu — Jubereq — C9399 / J3590
- Denosumab-dssb — Xbryk — Q5159
- Denosumab-kyqq — Aukelso — Q5161
- Denosumab-mobz — Oziltus — C9399 / J3590
- Denosumab-nxxp — Bilprevda — Q5162
- Denosumab-qbde — Xtrenbo — C9399 / J3590

J0897	PROLIA	DENOSUMAB	Subcutaneous

Prolia and Associated Biosimilars (J0897)

- Denosumab — Prolia — J0897
- Denosumab-adet — Ponlimsi — C9399 / J3490 / J3590 / J9999
- Denosumab-bbdz — Jubbonti — Q5136
- Denosumab-bmwo — Stoboclo — Q5157
- Denosumab-bnht — Conexxence — Q5158
- Denosumab-desu — Osvyrti — C9399 / J3590
- Denosumab-dssb — Ospomyv — Q5159
- Denosumab-kyqq — Bosaya — Q5161
- Denosumab-mobz — Boncresa — C9399 / J3590
- Denosumab-nxxp — Bildyos — Q5162
- Denosumab-qbde — Enoby — C9399 / J3590

Policy Maintenance

This policy shall be reviewed at minimum annually or upon any of the following: addition/removal of drugs from the list, material NCCN or FDA guideline changes, changes in CMS reimbursement policy, material changes in Preferred vs. Non-Preferred cost differentials, or audit findings indicating systemic non-compliance.