TRS-ActiveCare Administrative Policy

Medical Benefit Medication Administration – Site of Care

(Select Non-Oncology Medications)

Policy Number	ADMMEDSOC001-TRS
Effective Date	09/01/2026
Review Cycle	Annual or as otherwise directed by TRS
Applies To	TRS-ActiveCare members
Policy Type	Administrative / Site-of-Care Policy

1. Purpose and Intent

This administrative policy establishes site-of-care criteria for administration of medical benefit medications identified by TRS as subject to this policy and listed in an active appendix.

The objectives of this policy are to:

- Direct medication administration to lower-level outpatient settings when available and clinically appropriate;
- Reduce avoidable utilization of hospital outpatient departments;
- Preserve hospital outpatient coverage when a defined site-of-care exception applies;
- Apply general site-of-care stipulations consistently across select non-oncology medications; and
- Clarify that site-of-care review governs where a covered service may be administered and is separate from whether the medication is medically necessary or otherwise covered.

This policy governs where a service is covered. It does not determine whether a medication is medically appropriate, whether the medication itself is covered, or whether other benefit or administrative review requirements are satisfied.

2. Policy Scope

This policy applies to infused or injected medications billed under the medical benefit and expressly identified in an active TRS-approved appendix.

A medication is subject to this policy only when it is listed in an active appendix. Appendices may identify individual medications, drug classes, subclasses, indications, or product-specific site-of-care rules.

This policy applies to requests involving hospital outpatient departments, physician offices or clinic-based infusion settings, freestanding non-hospital infusion centers, and home infusion settings, when applicable.

This policy includes select non-oncology medications. Skyrizi® (risankizumab) and Tremfya® (guselkumab), when listed in Appendix A, are treated as select non-oncology medications for purposes of this site-of-care policy.

3. Definitions

Term	Definition
Hospital Outpatient Setting	A department of, or facility affiliated with, an acute care hospital that bills as a hospital outpatient department, including but not limited to Place of Service 22 and associated revenue codes.

Lower-Level Setting	A non-hospital-affiliated site capable of administering the listed medication, including a physician office or clinic, freestanding non-hospital infusion center, or qualified home infusion provider when available and appropriate.
Listed Medication	A medication expressly identified in an active TRS-approved appendix as subject to this policy.
Select Non-Oncology Medication	A non-oncology medication administered by infusion or injection and expressly identified in an active TRS-approved appendix as subject to this policy.
Site-of-Care Exclusion	A plan design determination that services rendered in a specified setting are not covered unless a defined exception applies.
Exception	An approved benefit exception that permits coverage of a listed medication in a hospital outpatient setting that would otherwise be excluded under this site-of-care policy.

4. Core Site-of-Care Administration

4.1 Default Administration Position

Administration of a listed medication in a hospital outpatient setting is excluded from coverage unless a site-of-care exception has been approved under this policy and any applicable appendix.

Coverage may be available when a listed medication is administered in a lower-level setting, subject to all other applicable benefit provisions, medical policy requirements, administrative review requirements, and claims adjudication rules.

4.2 Preferred Lower-Level Outpatient Sites of Care

- Physician office or clinic-based infusion suite;
- Freestanding, non-hospital-affiliated infusion center;
- Qualified home infusion setting, when operationally available and clinically appropriate.

4.3 Non-Covered Site of Care Without Approved Exception

Hospital outpatient departments are non-covered for listed medications unless an approved exception applies.

5. General Site-of-Care Exception Framework

A listed medication may be covered in a hospital outpatient setting when records support that at least one qualifying clinical, safety, operational, or access condition is met. The request must identify the applicable exception criterion and include supporting documentation.

5.1 General Exception Criteria — At Least One Required

1. **Prior significant administration reaction.** History of a moderate or severe infusion or injection-related reaction, anaphylaxis, or other clinically significant administration-related event requiring enhanced monitoring beyond routine lower-level outpatient capabilities.
2. **Clinical instability requiring enhanced monitoring.** The member's current condition requires immediate access to hospital-level monitoring, equipment, or staff during administration.
3. **Combination regimen requiring hospital outpatient administration.** The requested medication is administered on the same date of service as one or more additional infused or injected medications or

services that, by benefit design or documented clinical requirement, are covered only when administered in a hospital outpatient setting, and separation across sites is not clinically or operationally appropriate.

4. **Complex or high-risk administration.** Clinical characteristics of the medication or patient require direct supervision with rapid access to emergency services or hospital-level intervention.
5. **Re-initiation after interruption.** The requested service is the first dose or early re-initiation dose following a prolonged interruption due to prior adverse reaction, clinical instability, or hospitalization, and documentation supports enhanced monitoring.
6. **Access limitation.** No qualifying lower-level outpatient site of care capable of administering the medication is available within the applicable access standard, including the seventy-five (75) mile specialty care distance standard when applicable, or within a timeframe consistent with the treatment schedule.
7. **Home administration not appropriate.** The home setting is not suitable due to safety, caregiver availability, environmental concerns, or inability to meet required administration or monitoring needs when home infusion is the only otherwise available lower-level option.
8. **Appendix-specific criterion.** The member meets an additional or modified medication-specific criterion in the applicable appendix.

5.2 Factors Not Sufficient Alone to Justify Hospital Outpatient Use

The following factors, in isolation and without documentation showing a qualifying clinical, safety, operational, or access condition, do not support hospital outpatient administration:

- Generalized “high-risk” designation without documented instability or need for hospital-level intervention;
- Stable chronic conditions without evidence of imminent administration-related risk;
- Convenience, provider preference, member preference, routine monitoring needs, or historical use of a hospital outpatient department;
- Transportation barriers, missed appointments, or generalized social concerns, unless documentation demonstrates a specific material safety risk that cannot be mitigated in a lower-level setting and requires hospital-level resources at the time of administration.

5.3 Duration of Exception Approval

Exception duration is medication-specific and is defined in the applicable appendix. If an appendix does not establish a medication-specific duration, the approved duration should be limited to the period clinically or operationally necessary to address the documented site-of-care exception and may be subject to re-evaluation based on updated documentation.

5.4 Relationship to Medication-Specific Appendices

Additional medication-specific, class-specific, or indication-specific site-of-care criteria may be described in the relevant appendix. In the event of conflict, the appendix governs for that medication or class, while the core policy governs for all other provisions.

6. Benefit Review and Documentation

- Hospital outpatient administration of a listed medication requires review and approval of a site-of-care exception before the requested hospital outpatient service is covered.
- Requests must identify the requested medication, requested site of care, lower-level outpatient sites considered, anticipated date of service, and the applicable exception criterion.
- Requests must include documentation sufficient to substantiate eligibility under this policy and any applicable appendix.
- Approval authorizes the site of care only and does not grant or deny coverage of the medication itself.

6.1 Documentation Requirements

- Recent provider progress note or clinical summary;
- Administration history, including prior infusion or injection reactions when applicable;
- Treatment regimen details and anticipated administration schedule;
- Clinical rationale for hospital outpatient administration;
- Documentation of lower-level site availability or access limitations when access is the basis of the request;
- Other supporting records relevant to the requested exception.

7. Claims Processing

- Claims for hospital outpatient administration of a listed medication without an approved site-of-care exception will be denied as non-covered for the requested site of care.
- Claims with an approved exception will adjudicate according to the member's applicable plan benefits.
- Member and provider communications should distinguish a site-of-care denial from a medication medical-necessity or drug-coverage denial.

8. Appeals

- Appeals of a site-of-care denial will be evaluated against the applicable TRS benefit provisions, this policy, and any applicable appendix.
- A site-of-care denial does not determine whether the medication is medically necessary or otherwise covered in a lower-level setting.

9. Relationship to Appendices

- Appendices are incorporated by reference and identify the medications, drug classes, subclasses, or indications subject to this policy.
- A medication is not subject to this policy unless it is listed in an active TRS-approved appendix.
- Appendices may define additional medication-specific or class-specific exception criteria and establish rules unique to a medication or subclass.
- Appendices may be added, revised, or retired independently of the core policy when approved by TRS. In the event of conflict, the appendix governs for that medication or class, while the core policy governs for all other provisions.

10. Limitations

This policy:

- Does not assess medical necessity of the medication or therapeutic treatment;
- Does not determine drug coverage or indication approval;
- Does not apply to inpatient admissions;
- Does not override the member's benefit plan document;
- Does not require coverage of hospital outpatient administration when a qualifying site-of-care exception is not documented.

11. Policy History

Date	Description
Draft	Draft policy under development; not active.

Appendix A — Skyrizi® (Risankizumab) and Tremfya® (Guselkumab) Site-of-Care Rules

A.1 Listed Medications

This appendix applies to Skyrizi® (risankizumab) and Tremfya® (guselkumab) when administered under the TRS-ActiveCare medical benefit for ulcerative colitis or Crohn's disease.

Skyrizi and Tremfya are select non-oncology medications for purposes of this policy.

A.2 Default Administration Position

Administration of Skyrizi or Tremfya in a hospital outpatient setting is not covered unless a site-of-care exception is approved under this policy.

Covered lower-level outpatient sites include physician office or clinic-based administration, freestanding non-hospital infusion center, and qualified home infusion when available and clinically appropriate.

A.3 Indication Requirement for This Appendix

This appendix applies only when Skyrizi or Tremfya is requested for ulcerative colitis or Crohn's disease. Site-of-care review under this appendix does not determine whether Skyrizi or Tremfya is covered for the requested indication.

A.4 Skyrizi/Tremfya-Specific Site-of-Care Criteria

No additional medication-specific site-of-care criterion is required beyond the General Site-of-Care Exception Framework in Section 5 unless TRS adopts additional criteria for this appendix. For Skyrizi and Tremfya, any approved hospital outpatient site-of-care exception under this appendix is limited to the intravenous induction phase described in Section A.5.

Subcutaneous maintenance administration is not eligible for hospital outpatient site-of-care exception coverage under this appendix unless TRS adopts separate criteria for that use.

A.5 Duration of Skyrizi/Tremfya Site-of-Care Exception

For Skyrizi and Tremfya, any approved hospital outpatient site-of-care exception is limited to the first three intravenous induction doses only.

For Skyrizi, the IV induction doses occur at Week 0, Week 4, and Week 8 for Crohn's disease or ulcerative colitis. Maintenance therapy begins as subcutaneous administration at Week 12 and every 8 weeks thereafter.

For Tremfya, the IV induction doses occur at Week 0, Week 4, and Week 8 for Crohn's disease or ulcerative colitis. Maintenance therapy is administered subcutaneously according to the applicable maintenance schedule.

Approval under this appendix does not extend to subcutaneous maintenance doses.

A.6 Documentation Specific to Skyrizi/Tremfya Requests

- Medication requested: Skyrizi® (risankizumab) or Tremfya® (guselkumab);
- Approved indication for this appendix: ulcerative colitis or Crohn's disease;
- Requested IV induction dose number and anticipated date of service;
- Requested site of care and lower-level outpatient sites considered;
- Supporting explanation and records for the applicable general exception criterion.

A.7 Relationship to Core Policy

All provisions of ADMMEDSOC001-TRS apply unless modified by this appendix.

Appendix Structure for Future Use

TRS may add future appendices to identify additional medications or medication classes subject to this policy. Future appendices are not effective unless adopted by TRS.

- Appendix B — Additional Select Non-Oncology Medical Benefit Medications.