Allergen Subcutaneous Immunotherapy (SCIT)

MEDICAL POLICY NUMBER: 448

Effective Date: 1/1/2026

Last Review Date: 10/2025

Next Annual Review: 11/2026

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Note:

- This policy does not address: allergy immunotherapy administered via oral and nasal routes (ex. Oralair®, Grastek®, Ragwitek®, and Odactra®) and food allergy treatments (ex. Palforzia®).

Office- or facility-based Subcutaneous Immunotherapy (SCIT)

I. Office- or facility-based subcutaneous immunotherapy may be considered **medically necessary** for the treatment of allergic conditions when **all** of the following criteria (A.-D.) are met:
   A. The allergy is IgE-mediated as documented by skin testing or RAST; **and**
   B. The symptoms are not easily controlled with medication; **and**
   C. The symptoms encompass more than one season; **and**
   D. The therapy is ordered by a healthcare provider licensed and trained in allergy immunotherapy.

II. Office- or facility-based subcutaneous immunotherapy is considered **not medically necessary** for the treatment of allergic conditions when criterion I. above is not met.

Home-based Subcutaneous Immunotherapy (SCIT)

III. Home-based subcutaneous immunotherapy (not including rapid desensitization) for the treatment of allergic conditions may be considered **medically necessary** on an individual basis after case review (See *Policy Guidelines*).

IV. In the absence of an individual exception being made, home-based subcutaneous immunotherapy (not including rapid desensitization) is considered **not medically necessary**.

Rapid Desensitization

V. Rapid desensitization (also known as rush, cluster, or acute desensitization) (CPT 95180) for the treatment of allergic conditions may be considered **medically necessary** when the patient meets **at least one** of the following criteria (A.-C.):
   A. Allergy to a particular drug for a condition that cannot be treated effectively with alternative medications; **or**
   B. Insect sting (e.g., wasps, hornets, bees, fire ants) hypersensitivity (Hymenoptera); **or**
   C. Members with moderate to severe allergic rhinitis who need treatment during or immediately before the season of the affecting allergy when avoidance or pharmacotherapy failed to control symptoms.

VI. Rapid desensitization for the treatment of allergic conditions is considered **not medically necessary** when criterion IV. above is not met.

VII. Home-based rapid desensitization is considered **not medically necessary**.

Limitations

VIII. CPT code 95165 is limited to 150 units per 12 months per year (i.e., rolling 12 months). Utilization exceeding this limit is **not medically necessary**.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Allergy Testing, MP153

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- All medical records and chart notes pertinent to the request. This includes:
    - Medical history, examination, and results of diagnostic testing (including allergy testing) upon which the need for the treatment is based.
    - Treatment plan and dosage regimen must be documented in the member's medical record. The physician prescribing immunotherapy should be trained and experienced in prescribing and administering immunotherapy, selecting the appropriate allergen extracts based on the individual patient's clinical history and allergen exposure history, as well as the results of tests for specific IgE antibodies.
    - For post-service reviews, documentation must support the use of the code submitted (e.g., number of venoms, number of vials, etc.).

BACKGROUND

Subcutaneous Allergen Immunotherapy (SCIT)

An allergy is an abnormal reaction or increased sensitivity to certain substances in the environment. Substances that cause this sensitivity or reaction are called allergens and may vary from naturally occurring materials, such as pollen and grass, to man-made materials, such as soaps or chemicals. First-line treatment includes avoidance and minimization of exposure when possible. Medication, including antihistamines, bronchodilators, leucotriene inhibitors, and steroids (cortisone), may be used to reverse some of the symptoms of allergic reactions.

SCIT is an established treatment option designed to prevent or lessen an allergic reaction.[1-3] Its mechanism of action is based upon the body's production of different antibodies to an antigen depending on how the antigen is introduced into the body. It is typically used in individuals after a trial of conservative treatment, such as avoidance and medications, has been found to be inadequate. Allergy immunotherapy does not cure allergies; immunotherapy aims to make a person less sensitive to allergens. In some cases, allergic symptoms may be controlled to the point of disappearance, allowing a person to avoid allergen reactions. Subcutaneous allergy immunotherapy has been used for the management of allergic rhinitis, allergic conjunctivitis, allergic asthma, and hymenoptera (stinging insect) sensitivity.

Allergy immunotherapy consists of two phases which are referred to as the build-up phase and the maintenance phase. The build-up phase begins with exposure to very low doses of the allergen in an attempt to prevent serious reactions and progresses gradually to increased doses typically injected 1 to 3 times per week. This allows the body to slowly develop immunity to the antigen with minimal or no adverse symptoms. After a period of time, an effective dose of antigen is reached, and injections are typically maintained at this dosage. The length of this period depends upon how often injections are given but generally ranges from 8 to 28 weeks. The effective maintenance dose depends on a person's response to the build-up phase and degree of allergen sensitivity. During the maintenance phase, the period of time between treatments can be longer and can range from 2 to 4 weeks.

A reaction to allergy immunotherapy treatment can occur immediately following an injection, or it may be delayed for up to 24 hours. Most reactions are local, such as itching, pain and swelling. Occasionally,

more severe reactions, such as hives or shock, may occur. The most severe reactions usually occur within the first 30 minutes after an injection; reactions occurring after that time are generally mild. To monitor these effects, treatment is given in a medical office or facility with medical supervision. Environmental interventions, such as avoidance of allergens, and medications may be used in conjunction with allergy immunotherapy.

Home Immunotherapy

According to guidelines from the American Academy of Asthma, Allergy and Immunotherapy, frequent or routine home immunotherapy is not considered appropriate under any circumstances.[4] Allergen immunotherapy should be administered in a medical office or facility setting, with trained staff and medical equipment capable of recognizing and treating anaphylaxis.

However, in rare and exceptional cases when allergen immunotherapy cannot be administered in a medical facility and withholding this therapy would result in a serious detriment to the patient's health, careful consideration of potential benefits and risks of at-home administration of allergen immunotherapy can be made on an individual basis. Reasonable exceptions include, but may not be limited to, the following:

- Patients with a history of venom-induced anaphylaxis and who live in a remote region.
- Patients who are elderly, disabled, or live in rural areas.
- Patients who are immunocompromised or at high risk of infection.

Should home administration be deemed necessary and utilized, in addition to the "Documentation Requirements" noted above, the following requirements must be present in the record:

A. Adequate documentation indicating why home administration is needed;
B. Documentation indicating the member or adult household member has been properly trained in recognizing and treating anaphylactic and/or allergic reactions to allergy immunotherapy administration;
C. Epinephrine kits must be available and the member or adult household member has been instructed in its use;
D. Documentation that the member or adult household member has been properly trained in antigen(s) dosing plan, withdrawing of correct amount of antigen(s) from the vial and administration of allergy immunotherapy;
E. Signed consent by the member or adult household member to administer allergy immunotherapy at home;
F. Documentation that the provider initiated allergy immunotherapy in their office (only continued therapy is planned for the member's home); and
G. Signed acknowledgement by the member or adult household member of receiving antigen vial(s) as per the individualized treatment protocol.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of subcutaneous allergen immunotherapy as a treatment for allergies Below is a summary of the available evidence identified through September of 2025.

Allergen Subcutaneous Immunotherapy (SCIT)

- In 2016, Tam and colleagues conducted a systematic review of randomized controlled trials evaluating the efficacy and safety of SCIT for the treatment of atopic eczema.[5] A total of 12 trials involving 733 participants were included, assessing SCIT administered via subcutaneous, sublingual, oral, or intradermal routes. Most studies focused on house dust mite sensitization. While investigator-rated disease severity and SCORAD scores showed modest improvement in some trials, participant-reported outcomes were inconsistent and overall inconclusive. Adverse events were comparable between SIT and control groups, though sublingual immunotherapy was associated with a higher rate of local reactions. The authors concluded that the evidence supporting SCIT for atopic eczema remains limited and of low quality, and further high-quality trials are needed to determine its clinical utility.

- In 2012, Boyle and colleagues completed a systematic review and meta-analysis of venom immunotherapy (VIT) for preventing allergic reactions to insect stings.[6] Seven trials were included, reporting on 392 participants with prior systemic or large local reactions to bee, wasp, or ant stings. VIT significantly reduced the risk of systemic reactions to subsequent stings, with a pooled relative risk of 0.10. Improvements were also observed in quality of life and reduction of large local reactions. However, no fatal reactions occurred in either treatment or control groups, and the impact of VIT on mortality could not be assessed. The authors noted a small but significant risk of systemic adverse reactions to VIT and emphasized the importance of individualized risk-benefit assessment when considering treatment.

- In 2010, Abramson and colleagues updated a comprehensive Cochrane review on injection allergen immunotherapy for asthma.[7] Eighty-eight randomized controlled trials were included, encompassing 3792 participants sensitized to allergens such as house dust mites, pollen, animal dander, and molds. Immunotherapy was associated with significant reductions in asthma symptoms, medication use, and allergen-specific bronchial hyperreactivity. However, there was no consistent improvement in lung function, and heterogeneity across studies was high. Systemic adverse reactions occurred in

approximately 20% of treated patients, with an estimated number needed to harm of 9. The authors concluded that while injection immunotherapy is effective for allergic asthma, its use should be carefully weighed against the risk of adverse events, and further research is needed to optimize dosing and identify patient subgroups most likely to benefit.

Rapid Desensitization

- In 2014, Feng and colleagues conducted a systematic review and meta-analysis of cluster SCIT for allergic rhinitis.[8] Eight randomized controlled trials involving 567 participants were included. Compared to conventional SCIT, cluster SCIT showed similar reductions in symptom and medication scores. However, when compared to placebo, no statistically significant improvements were observed in these outcomes. Cluster SCIT did improve quality of life in some studies. Safety analysis revealed no significant differences in local or systemic adverse reactions between cluster SCIT and control groups, and no grade 3 or 4 systemic reactions or fatalities were reported. The authors concluded that while cluster SCIT appears promising, further large-scale trials are needed to confirm its efficacy and safety.

- In 2018, Pimentel and colleagues completed a systematic review of accelerated SCIT schedules—rush and cluster protocols—for respiratory allergies in pediatric patients.[9] Eleven trials were included, with two evaluating rush SCIT and nine assessing cluster SCIT. Both schedules demonstrated clinical and immunological efficacy, with faster onset of benefits compared to conventional SCIT. No significant differences in outcomes were found between pediatric, adult, or mixed populations. Safety profiles were favorable, with most adverse reactions being mild and no life-threatening or fatal events reported. The authors emphasized the need for standardized protocols and further pediatric-specific trials to strengthen the evidence base.

CLINICAL PRACTICE GUIDELINES

Joint Expert Guideline

In 2024, Gurgel and colleagues published a clinical practice guideline on immunotherapy for inhalant allergy, developed by a multidisciplinary panel under the American Academy of Otolaryngology–Head and Neck Surgery Foundation.[10] The guideline targets patients aged 5 and older with allergic rhinitis (AR), with or without allergic asthma (AA), and provides 12 key action statements (KASs) to guide safe and effective use of allergen immunotherapy (AIT). Recommendations include offering AIT to patients with inadequately controlled symptoms, avoiding initiation in those with uncontrolled asthma or pregnancy, and educating patients on SCIT vs SLIT options. The guideline emphasizes individualized care, shared decision-making, and the importance of clinician preparedness to manage anaphylaxis. It also addresses treatment duration, allergen selection, and the potential preventive benefits of AIT. The authors highlight evidence gaps and propose future research directions to improve practice and outcomes.

The Joint Task Force on Practice Parameters (Representing the American Academy of Allergy, Asthma & Immunology (AAAAI); the American College of Allergy, Asthma & Immunology (ACAAI); and the Joint Council of Allergy, Asthma & Immunology)

The January 2011 update to the allergen immunotherapy practice parameters provides a comprehensive set of guidelines for the safe and effective use of allergen immunotherapy (AIT) in treating allergic conditions such as allergic rhinitis, asthma, and insect sting hypersensitivity.[4] Developed by a joint task force representing AAAAI, ACAAI, and JCAAI, the document outlines evidence-based recommendations for patient selection, dosing, extract preparation, and risk management. It introduces new indications for AIT, including atopic dermatitis with aeroallergen sensitivity and venom immunotherapy for recurrent large local reactions. The update emphasizes that there are no absolute age limits for initiating AIT and that treatment may be considered in special populations such as pregnant individuals, children under five, the elderly, and patients with HIV or autoimmune disorders. Safety protocols are reinforced, including a mandatory 30-minute post-injection observation period and careful assessment of asthma control before administration. The document also discusses the role of premedication (e.g., antihistamines, leukotriene antagonists, omalizumab) in reducing adverse reactions, and it reviews investigational non-injection routes like sublingual, oral, intralymphatic, and epicutaneous immunotherapy. Additionally, it provides detailed guidance on extract standardization, mixing principles, and documentation practices to minimize errors and optimize treatment outcomes.

EVIDENCE SUMMARY

Subcutaneous allergen immunotherapy (SCIT) has been evaluated across a range of allergic conditions, including atopic eczema, allergic rhinitis, asthma, and insect sting hypersensitivity. Evidence from systematic reviews and meta-analyses indicates that SCIT is effective in reducing asthma symptoms, medication use, and allergen-specific bronchial hyperreactivity, though improvements in lung function remain inconsistent. Venom immunotherapy (VIT) has demonstrated a significant reduction in systemic reactions to insect stings and improved quality of life, with a small but measurable risk of systemic adverse events. For atopic eczema, the evidence supporting SCIT is limited and of low quality, with inconsistent patient-reported outcomes and modest improvements in disease severity. Accelerated SCIT protocols, including cluster and rush schedules, have shown comparable efficacy to conventional SCIT, with faster onset of benefits and favorable safety profiles, particularly in pediatric populations. No life-threatening or fatal events were reported in these studies. Clinical practice guidelines from the American Academy of Otolaryngology–Head and Neck Surgery Foundation and the Joint Task Force on Practice Parameters support the use of SCIT in patients with allergic rhinitis and asthma who have inadequately controlled symptoms, while emphasizing individualized care, shared decision-making, and clinician preparedness to manage anaphylaxis. These guidelines also highlight the importance of allergen selection, treatment duration, and the potential preventive benefits of immunotherapy, while identifying key evidence gaps for future research.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that

influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

GENERAL

Frequency Limits

As with all medically necessary services, allergy immunotherapy is expected to be performed at frequencies as indicated by current medical literature and/or standards of practice. All units reported on any claim must be justified, and documentation must support the units of services rendered, that the services have been coded correctly, and that the services were medically reasonable and necessary for the individual.

The Centers for Medicare and Medicaid Services (CMS) has established medically unlikely edits (MUEs) for many of the services addressed by this medical policy. MUEs represent the maximum number of units for a service that would reasonably be reported for a service by the same provider, for the same member, on the same date of service. However, frequency limits found in this policy are based on clinical rationale and may diverge from the MUEs established by CMS.

In addition, all units for a service reported on any claim must be justified, meaning documentation must support the units of services rendered, that the services have been coded correctly, that the services were medically reasonable and necessary for the individual, and that the date of service on the claim aligns with the date the services were rendered to the patient. The date of service reported on a claim must match the actual date the services were rendered and be supported by the medical record. Reporting services provided on a single date across multiple claims using different service dates constitutes incorrect billing and is not appropriate. Units for allergen preparation should be billed on the preparation date and not split over subsequent days.

Coding Guidance

Subcutaneous allergen Immunotherapy (SCIT) is divided into categories of codes which are described as follows:

Table 1: Categories of SCIT Codes

Category	Codes	Notes
Complete Service	CPT 95120-95134	• Represent services that include the injection service (administration), the antigen and its preparation.
Injection Only	CPT 95115 & 95117	• Used for the professional administration (injection) of the allergenic extract. They do not include the provision or preparation of the extract. • Example: An allergist provides a patient with an allergenic extract, and the patient brings the extract to a family or primary care practitioner who administers the injection(s). These codes would be used by the family or primary care provider. • These codes should not be used if the antigen is self-administered by the member.
Antigen provision and preparation only	CPT 95144-95170	• Used when injection will be performed by a different physician, or will be self-administered by the member. • Used to report the antigen/antigen preparation service (professional services) when this is the only service rendered by the physician. • The code selected is based on the specific type of antigen provided: ○ CPT codes 95145-95149 and 95170 are used to report stinging insect venoms.

		○ CPT 95144 - used to report antigens, other than stinging insect. ○ CPT 95165 - used to report multiple dose vials of non-venom antigens. Considered single dose codes. This means providers must specify the number of doses provided.

Providers may use either complete service codes (95120-95134) OR a combination of injection (95115, 95117) and antigen (95144-95170) codes. Regardless of what methodology is used, coding must accurately represent the service(s) rendered to the patient and be supported by the medical record.

According to correct coding guidelines, component services deny as bundled to the comprehensive services when they are reported together. Therefore, CPT codes 95115-95117 and 95144-95170 deny as bundled when reported with CPT codes 95120-95134.

CPT 95165: Note that the number of units is not based on the estimated number of injections. Rather, it is based on the number of 1-cc doses in the vial, and Medicare defines a dose as a "1-cc aliquot from a single multidose vial."

If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes may be reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered.

Allergen Immunotherapy in the Home

While home allergen immunotherapy should **not** be used as standard care, for patients who receive allergy immunotherapy in the home and when such is supported by the clinical documentation, the supplying physician can bill for the **preparation and provision** of the immunotherapy antigens, but they are able to submit claims for the **administration**, since patient is performing the administration on themselves.

CODES*		
CPT	95115	Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection
	95117	Professional services for allergen immunotherapy not including provision of allergenic extracts; 2 or more injections
	95120	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; single injection

	95125	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 2 or more injections
	95130	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; single stinging insect venom
	95131	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 2 stinging insect venoms
	95132	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 3 stinging insect venoms
	95133	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 4 stinging insect venoms
	95134	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 5 stinging insect venoms
	95144	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vial(s) (specify number of vials)
	95145	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); single stinging insect venom
	95146	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 2 single stinging insect venoms
	95147	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 3 single stinging insect venoms
	95148	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 4 single stinging insect venoms
	95149	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 5 single stinging insect venom
	95165	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)
	95170	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; whole body extract of biting insect or other arthropod (specify number of doses)
	95180	Rapid desensitization procedure, each hour (eg, insulin, penicillin, equine serum)
	95199	Unlisted allergy/clinical immunologic service or procedure
HCPCS	None	

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.

- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2026	New policy.