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National Government Services (NGS) Medical Policy Unit
P.O. Box 7108
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Submitted Electronically: NGSDraftLCDComments@anthem.com

RE: Proposed Local Coverage Determination (LCD) DL40330 Allergy Diagnostic Testing and draft Billing and Coding Article DA60377

Dear NGS Medical Directors,

On behalf of the American Academy of Dermatology Association (AADA) and the Dermatologic Medicare Contractor Advisory Committee (DermCAC), thank you for the opportunity to comment on the Proposed LCD DL40330 Allergy Diagnostic Testing and draft Billing and Coding Article DA60377.

The AADA is the leading society in dermatological care, representing more than 17,500 dermatologists nationwide. The AADA is committed to excellence in the medical and surgical treatment of skin disease; advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of skin disease. The DermCAC is a national coalition of dermatologist representatives selected by their state dermatology societies and represents the board-certified dermatologists in your carrier region. The DermCAC aims to collaborate with Medicare Administrative Contractors to establish reasonable, fair policies that prioritize patient well-being.

The AADA and DermCAC appreciate NGS's recognition of patch testing as the gold standard for diagnosing allergic contact dermatitis (ACD) and its acknowledgement that comprehensive patch testing may be necessary in certain clinical scenarios. We submit the following comments to address specific provisions of the proposed LCD and associated Billing and Coding Article that are inconsistent with current clinical standards for comprehensive patch testing and may affect access to medically necessary allergy diagnostic testing, if finalized as written.

I. Ensure Access to Comprehensive Patch Testing Based on All Available Literature and Clinical Standards

The AADA and DermCAC are concerned that the proposed LCD relies on older literature to support patch testing coverage that recommends testing up to 65 contactant allergens¹, despite more recent peer-reviewed literature and clinical data supporting comprehensive patch testing with 80–90 allergens for the diagnosis of ACD.

We appreciate that the proposed LCD recognizes that customized or supplemental patch testing beyond a standard screening panel is often required based on a patient's exposure history. We also acknowledge that the policy, if finalized, would allow up to 80 tests or allergens when medically necessary. However, the *Evidentiary Analysis* and *Rationale for Determination* sections rely on literature that established a 65-allergen threshold and do not incorporate more recent evidence supporting more comprehensive and individualized testing.

Patch testing is a cornerstone diagnostic tool in dermatology for identifying ACD, a common condition with significant clinical, occupational, and quality-of-life implications when not accurately diagnosed. Comprehensive patch testing combines a standardized screening panel with supplemental allergens selected based on patient-specific factors, including exposure history, occupational risk, and physical examination.^{2,3,4}

Comprehensive patch testing is widely recognized as a cost-effective diagnostic tool and has been shown to identify clinically relevant allergens that may not be detected when testing to targeted panels or a more limited set of allergens.^{2,3,4} Multiple studies demonstrate that limited allergen panels may miss approximately 40–48% of clinically relevant allergens detected using broader screening series.^{2,5} Even testing limited to an 80-allergen series alone may fail to identify relevant allergens in a meaningful subset of patients.^{2,5} Many of the allergens identified beyond 80-allergen screening panels are occupational, and ACD in certain occupations may be missed with an 80-allergen screening series alone.

¹ In patch testing, many of the substances applied to the skin are small, low-molecular-weight chemicals often described in the scientific literature as “haptens.” This letter uses the term “allergen” to remain consistent with the terminology used in the proposed LCD.

² Chen, J.K. et al. (2025). The importance of comprehensive patch testing: A call to action from the American Contact Dermatitis Society. *Journal of the American Academy of Dermatology*, S0190-9622(25):3280-3. DOI: [10.1016/j.jaad.2025.11.067](https://doi.org/10.1016/j.jaad.2025.11.067)

³ Zhu T.H. et al. (2018). The medical necessity of comprehensive patch testing. *Dermatitis*, 29(3):107-111. DOI: [10.1097/DER.0000000000000362](https://doi.org/10.1097/DER.0000000000000362)

⁴ Warshaw, E.M. et al (2021). Importance of supplemental patch testing beyond a screening series for patients with dermatitis: the North American contact dermatitis group experience. *JAMA Dermatol*, 157(12):1456-1465. DOI: [10.1001/jamadermatol.2021.4314](https://doi.org/10.1001/jamadermatol.2021.4314)

⁵ Houle, Marie-Claude, et al. (2025). North American Contract Dermatitis Group Patch Test Results: 2021-2022. *Dermatitis*, (36)5, 464-476. DOI: [10.1089/derm.2024.0474](https://doi.org/10.1089/derm.2024.0474)

In contrast, the discussions in the proposed LCD's *Evidentiary Analysis* and *Analysis of Evidence* sections only reference screening panels addressing up to 65 allergens, with the *Evidentiary Analysis* stating the following and similar language included in the *Analysis of Evidence*:

“Because ACD is frequently caused by unsuspected substances, up to 65 patch tests may be required for diagnosis. Supplementary patch tests are often required as suggested by the patient’s exposure history, and up to 65 contactant tests are recommended by the North American Contact Dermatitis Research Group.”

This cited recommendation does not reflect current clinical practice or updated standards. The North American Contact Dermatitis Group (NACDG) standardized screening series currently includes 80 allergens.⁶ 2025 NACDG case study data show that more than 20% of patients have clinically relevant allergic reactions to allergens not included in the screening series, indicating that additional testing is commonly required to establish an accurate diagnosis.⁶ The American Contact Dermatitis Society (ACDS) Core Allergen Series, updated in 2020, includes 90 allergens.⁷ The Centers for Medicare & Medicaid Services (CMS) has similarly recognized the clinical appropriateness of comprehensive patch testing through the Medically Unlikely Edit (MUE) for CPT code 95044 (patch or application test), which allows up to 90 units effective July 1, 2022.⁸

Comprehensive patch testing is frequently necessary for patients in whom allergic contact dermatitis is caused by unsuspected substances, exposures involve multiple potential contactants, or prior limited skin patch testing fails to identify the relevant trigger. The number of allergens tested is driven by patient-specific clinical factors and guided by clinical judgment.

While the proposed coverage guidance allows for up to 80 tests, continued reliance on older literature recommending a 65-allergen threshold is not an appropriate clinical benchmark for comprehensive patch testing and does not reflect current clinical standards, contemporary screening series, or evidence-based practice. This reliance also creates ambiguity regarding the standard that will be applied in medical review and audit settings. In practice, this discrepancy may result in denials or payment reductions for medically appropriate comprehensive patch testing, thereby creating unintended barriers to patient access when individualized testing is clinically necessary. CMS directs Medicare Administrative Contractors to base LCDs on available

⁶ Houle, Marie-Claude, et al. (2025). North American Contact Dermatitis Group Patch Test Results: 2021-2022. *Dermatitis*, (36)5, 464-476. DOI: [10.1089/derm.2024.0474](https://doi.org/10.1089/derm.2024.0474)

⁷ Schalock, Peter C., et al. (2020). American Contact Dermatitis Society Core Allergen Series: 2020 Update. *Dermatitis*, 31(5), 279–282. DOI: [10.1097/DER.0000000000000621](https://doi.org/10.1097/DER.0000000000000621)

⁸ Medicare NCCI Medically Unlikely Edits Archive. Practitioner Services Effective July 1, 2022. Accessed February 1, 2026: <https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medicare-ncci-medically-unlikely-edit-mue-archive>

evidence that reflects general acceptance within the medical community, including peer-reviewed clinical studies, evidence-based consensus statements, and clinical guidelines.⁹

To ensure continued access to comprehensive patch testing, the AADA and DermCAC urge NGS to update the supporting literature cited in the LCD to reflect current evidence and clinical standards, as outlined in the peer-reviewed studies and clinical resources provided in Appendix A.

We also encourage NGS to review and update the number of patch tests allowed so the stated “up to” threshold reflects current clinical practice and the available peer-reviewed evidence. As described in the supporting discussion above, contemporary clinical standards for comprehensive patch testing support allowance of testing up to 80–90 allergens, when medically necessary. Aligning the evidence cited in the policy and the “up to” threshold with current clinical standards, CMS guidance, and Medicare Part B claims edits would improve clarity and support appropriate access to medically necessary comprehensive patch testing.

II. Clarification and Conditional Revision of Limitations Related to Skin Patch Testing for Formaldehyde

As written, the proposed LCD is unclear as to whether skin patch testing for ACD due to formaldehyde is covered. Under *Limitations* in the proposed LCD, NGS states that “*allergy testing for substances such as newsprint, sugar, cornstarch, orris root, tobacco smoke, cotton, formaldehyde, and smog is not supported by evidence and hence is not covered.*” It is not clear whether this limitation applies to skin patch testing for ACD.

Formaldehyde is well-recognized as a common trigger for ACD and is found in a wide range of common household products, including glues, paints, and paper products.¹⁰ Formaldehyde-releasing preservatives are also used in some medications, cosmetics, and other consumer products like dishwashing liquids and fabric softeners.¹⁰ Formaldehyde is also included in many standard allergen panels, including the FDA-approved Thin-Layer Rapid Use Epicutaneous (T.R.U.E.) Test¹¹ and the ACDS Core Allergen Series.¹²

⁹ Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determination §13.5.3 Evidentiary Content. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloadws/pim83c13.pdf>

¹⁰ United States Environmental Protection Agency. (2025, July 7). Facts About Formaldehyde. Accessed January 27, 2026. <https://www.epa.gov/formaldehyde/facts-about-formaldehyde>

¹¹ Package Insert Thin-Layer Rapid Use Epicutaneous (T.R.U.E.) Test. (2019). Accessed January 27, 2026. <https://www.fda.gov/vaccines-blood-biologics/allergenics/true-test>

¹² Schalock, Peter C., et al. (2020). American Contact Dermatitis Society Core Allergen Series: 2020 Update. *Dermatitis*, 31(5), 279–282. DOI: [10.1097/DER.0000000000000621](https://doi.org/10.1097/DER.0000000000000621)

The AADA and DermCAC urge NGS to update the LCD to clarify that skin patch testing can be used to diagnose ACD caused by formaldehyde or formaldehyde-releasing preservatives.

III. Revise Application of Generally Accepted Testing Standards to Include Skin Patch Testing

The proposed LCD outlines generally accepted professional testing standards for certain allergy testing modalities but does not clearly extend these best practices to skin patch testing. Under the *Limitations* section, NGS states that *"the total number of tests, i.e., prick or intracutaneous, should not exceed generally accepted standards of testing set forth by professional associations,"* with additional testing permitted when preliminary testing fails and documentation of medical necessity is provided. This provision references prick and intracutaneous testing but does not explicitly include skin patch testing.

Skin patch testing is a distinct diagnostic service with its own generally accepted professional standards, which guide both allergen selection and the number of tests performed based on clinical indication. Applying this principle to patch testing would be consistent with how the LCD addresses other forms of allergy testing and would provide clarity regarding the appropriate use of this diagnostic tool.

If finalized as written, this provision—particularly when considered alongside the LCD's reliance on literature reflecting more limited allergen testing—could be applied in a manner that limits access to comprehensive patch testing, even when additional testing is clinically indicated and supported by current literature and clinical guidelines.

We urge NGS to revise this limitation to explicitly include skin patch testing, clarifying that patch testing should be performed in accordance with generally accepted professional standards, while maintaining appropriate allowance for additional testing when clinically indicated and supported by documentation of medical necessity.

IV. Revise the Billing and Coding Article to Add Select ICD-10-CM Diagnosis Codes That Support Medical Necessity for CPT 95044

Based on the coverage indications described in the proposed LCD, patch testing is covered for patients presenting with a range of chronic, pruritic, eczematous, lichenified dermatitis when underlying or secondary ACD is suspected.

The AADA and DermCAC request that the ICD-10-CM codes identified below, which describe presenting conditions for which patch testing is covered under the LCD, be added

to Group 2 of the Billing and Coding Article DA60377 as supporting medical necessity for CPT code 95044.

ICD-10-CM Code	Description
L20.9	Atopic dermatitis, unspecified
L23.9	Allergic contact dermatitis, unspecified cause
L25.9	Unspecified contact dermatitis, unspecified cause
L28.0	Lichen simplex chronicus
L29.89	Other pruritus
L29.9	Pruritus, unspecified
L30.9	Dermatitis, unspecified
H01.111	Allergic dermatitis of right upper eyelid
H01.112	Allergic dermatitis of right lower eyelid
H01.113	Allergic dermatitis of right eye, unspecified eyelid
H01.114	Allergic dermatitis of left upper eyelid
H01.115	Allergic dermatitis of left lower eyelid
H01.116	Allergic dermatitis of left eye, unspecified eyelid
H01.119	Allergic dermatitis of unspecified eye, unspecified eyelid
H01.131	Eczematous dermatitis of right upper eyelid
H01.132	Eczematous dermatitis of right lower eyelid
H01.133	Eczematous dermatitis of right eye, unspecified eyelid
H01.134	Eczematous dermatitis of left upper eyelid
H01.135	Eczematous dermatitis of left lower eyelid
H01.136	Eczematous dermatitis of left eye, unspecified eyelid
H01.139	Eczematous dermatitis of unspecified eye, unspecified eyelid

The AADA and DermCAC appreciate the opportunity to provide feedback on the proposed LCD DL40330 Allergy Diagnostic Testing. If you have any questions or would like more information about the comments in this letter, please contact Cameron Huff, MHA, Manager, Payment Policy at chuff@aad.org. We welcome the opportunity to discuss this further and appreciate your consideration of these comments.

Sincerely,



Susan C. Taylor, MD, FAAD

President, American Academy of Dermatology / Association



Howard Wooding Rogers, MD, PhD, FAAD

Chair, Dermatologic Medicare Contractor Advisory Committee

Appendix A

Additional Evidence to Support Coverage Guidance for Allergy Diagnostic Testing

Atwater AR, et al. Supplemental patch testing identifies allergens missed by standard screening series. *Dermatitis*.vol.35,4 (2024): 366-372.

<https://doi.org/10.1089/derm.2023.0310>

Chen, Jennifer K, et al. The Importance of Comprehensive Patch Testing: A Call to Action from the American Contact Dermatitis Society. *Journal of the American Academy of Dermatology*, S0190-9622(25)032803:3280-3, <https://doi.org/10.1016/j.jaad.2025.11.067>.

DeKoven, Joel G et al. North American Contact Dermatitis Group Patch Test Results: 2019-2020. *Dermatitis*. vol. 34,2 (2023): 90-104.

<https://doi.org/10.1089/derm.2022.29017.jdk>

Houle, Marie-Claude et al. North American Contact Dermatitis Group Patch Test Results: 2021-2022. *Dermatitis*. vol. 36,5 (2025): 464-476. doi:10.1089/derm.2024.0474

Rodriguez-Homs LG, et al. Patch test practice patterns of members of the American Contact Dermatitis Society. *Dermatitis*. vol. 31,4 (2020):272-275.

<https://doi.org/10.1097/der.0000000000000513>

Schalock PC, et al. American Contact Dermatitis Society core allergen series: 2020 update. *Dermatitis*. Vol. 31,5 (2020):279-282.

<https://doi.org/10.1097/DER.0000000000000621>

Warshaw EM, et al. Importance of supplemental patch testing beyond a screening series for patients with dermatitis: the North American Contact Dermatitis Group experience. *JAMA Dermatol*. 157,12 (2021):1456-1465.

<https://doi.org/10.1001/jamadermatol.2021.4314>