Local Coverage Determination (LCD): Therapeutic Shoes for Persons with Diabetes (L33369)

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Contractor Information

Contractor Name	Contract Type	Contract Number Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 - DME MAC J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC J-A	Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Utah Washington Wyoming Northern Mariana Islands

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LCD Information

Document Information

LCD ID
L33369

Original ICD-9 LCD ID
L27040
L11525
L11535
L157

LCD Title
Therapeutic Shoes for Persons with Diabetes

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 07/01/2016

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

CMS National Coverage Policy Medicare Benefit Policy Manual (IOM 100-02), Chapter 15, Section 140

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For

the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Medicare does not automatically assume payment for a durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) item that was covered prior to a beneficiary becoming eligible for the Medicare Fee For Service (FFS) program. When a beneficiary receiving a DMEPOS item from another payer (including Medicare Advantage plans) becomes eligible for the Medicare FFS program, Medicare will pay for continued use of the DMEPOS item only if all Medicare coverage, coding and documentation requirements are met. Additional documentation to support that the item is reasonable and necessary, may be required upon request of the DME MAC.

The statutory coverage criteria for therapeutic shoes including the requirement for an order are specified in the related Policy Article.

Separate inserts may be covered and dispensed independently of diabetic shoes if the supplier of the shoes verifies in writing that the beneficiary has appropriate footwear into which the insert can be placed. This footwear must meet the definitions found in this policy for depth shoes or custom-molded shoes.

A custom molded shoe (A5501) is covered when the beneficiary has a foot deformity that cannot be accommodated by a depth shoe. The nature and severity of the deformity must be well documented in the supplier's records and available upon request. If a custom molded shoe is provided but the medical record does not document why that item is medically necessary, it will be denied as not reasonable and necessary.

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph:

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

EY - No physician or other licensed health care provider order for this item or service

GA - Waiver of liability statement issued as required by payer policy, individual case

GY - Item or service statutorily excluded or does not meet the definition of any Medicare benefit

GZ - Item or service expected to be denied as not reasonable and necessary

KX - Requirements specified in the medical policy have been met

LT - Left Side

RT - Right Side

HCPCS CODES:

Group 1 Codes:

A5500	FOR DIABETICS ONLY, FITTING (INCLUDING FOLLOW-UP), CUSTOM PREPARATION AND SUPPLY OF OFF-THE-SHELF DEPTH-INLAY SHOE MANUFACTURED TO ACCOMMODATE MULTI-DENSITY INSERT(S), PER SHOE
A5501	FOR DIABETICS ONLY, FITTING (INCLUDING FOLLOW-UP), CUSTOM PREPARATION AND SUPPLY OF SHOE MOLDED FROM CAST(S) OF PATIENT'S FOOT (CUSTOM MOLDED SHOE), PER SHOE
A5503	FOR DIABETICS ONLY, MODIFICATION (INCLUDING FITTING) OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE WITH ROLLER OR RIGID ROCKER BOTTOM, PER SHOE
A5504	FOR DIABETICS ONLY, MODIFICATION (INCLUDING FITTING) OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE WITH WEDGE(S), PER SHOE
A5505	FOR DIABETICS ONLY, MODIFICATION (INCLUDING FITTING) OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE WITH METATARSAL BAR, PER SHOE
A5506	FOR DIABETICS ONLY, MODIFICATION (INCLUDING FITTING) OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE WITH OFF-SET HEEL(S), PER SHOE
A5507	FOR DIABETICS ONLY, NOT OTHERWISE SPECIFIED MODIFICATION (INCLUDING FITTING) OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE, PER SHOE
A5508	FOR DIABETICS ONLY, DELUXE FEATURE OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE, PER SHOE
A5510	FOR DIABETICS ONLY, DIRECT FORMED, COMPRESSION MOLDED TO PATIENT'S FOOT WITHOUT EXTERNAL HEAT SOURCE, MULTIPLE-DENSITY INSERT(S) PREFABRICATED, PER SHOE
A5512	FOR DIABETICS ONLY, MULTIPLE DENSITY INSERT, DIRECT FORMED, MOLDED TO FOOT AFTER EXTERNAL HEAT SOURCE OF 230 DEGREES FAHRENHEIT OR HIGHER, TOTAL CONTACT WITH PATIENT'S FOOT, INCLUDING ARCH, BASE LAYER MINIMUM OF 1/4 INCH MATERIAL OF SHORE A 35 DUROMETER OR 3/16 INCH MATERIAL OF SHORE A 40 DUROMETER (OR HIGHER), PREFABRICATED, EACH
A5513	FOR DIABETICS ONLY, MULTIPLE DENSITY INSERT, CUSTOM MOLDED FROM MODEL OF PATIENT'S FOOT, TOTAL CONTACT WITH PATIENT'S FOOT, INCLUDING ARCH, BASE LAYER MINIMUM OF 3/16 INCH MATERIAL OF SHORE A 35 DUROMETER OR HIGHER), INCLUDES ARCH FILLER AND OTHER SHAPING MATERIAL, CUSTOM FABRICATED, EACH

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph: For ICD-10 codes relating to statutory coverage, see Policy Article

Group 1 Codes: N/A

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph: Not specified

Group 1 Codes: N/A

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General Information

Associated Information

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

PRESCRIPTION (ORDER) REQUIREMENTS

GENERAL (PIM 5.2.1)

All items billed to Medicare require a prescription. An order for each item billed must be signed and dated by the prescribing practitioner, kept on file by the supplier, and made available upon request. Items dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

DISPENSING ORDERS (PIM 5.2.2)

Equipment and supplies that are NOT on the ACA 6407 list or that require a written order prior to delivery (WOPD) may be delivered upon receipt of a dispensing order (prescription). A dispensing order may be verbal or written. The supplier must keep a record of the dispensing order on file. It must contain:

- Description of the item
- Beneficiary's name
- Prescribing practitioner's name
- Date of the order and the start date, if the start date is different from the date of the order
- Prescribing practitioner's signature (if a written order) or supplier signature (if verbal order)

For the "Date of the order" described above, use the date the supplier is contacted by the prescribing practitioner's (for verbal orders) or the date entered by the prescribing practitioner's (for written dispensing orders).

In some cases, the prescribing practitioner may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of the order, date of service (DOS) entered on the claim, Medicare-required forms (e.g., CMN, DIF) or refill/delivery timelines. As long as the supplier has a properly completed dispensing order with a correctly determined prescription date, an item may be shipped or delivered on or after the date of the dispensing order (except for items that require written orders prior to delivery).

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The dispensing order must be available upon request.

For items that are provided based on a dispensing order, the supplier must obtain a detailed written order before submitting a claim.

DETAILED WRITTEN ORDERS (PIM 5.2.3)

A detailed written order (DWO) is required before billing. Someone other than the prescribing practitioner may produce the DWO. However, the prescribing practitioner must review the content and sign and date the

document. It must contain:

- Beneficiary's name
- Prescribing practitioner's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Prescribing practitioner's signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills

For the "Date of the order" described above, use the dispensing order date i.e., the date the supplier was contacted by the prescribing practitioner (for verbal orders) or the date entered by the prescribing practitioner (for written dispensing orders).

Additional order date instructions:

- If the prescriber creates a complete and compliant DWO, only a single date - the "order date" - is required. This order date may be the date that the prescriber signs the document (either wet signature or electronic signature).
- If someone other than the prescriber (e.g., DME supplier) creates the DWO then the prescription must be reviewed and, "…personally signed and dated…" by the prescriber. In this scenario, two (2) dates are required: an "order date" and a prescriber-entered "signature date".

In some cases, the prescribing practitioner may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of the order, date of service (DOS) entered on the claim, Medicare-required forms (e.g., CMN, DIF) or refill/delivery timelines. As long as the supplier has a properly completed dispensing order with a correctly determined prescription date, an item may be shipped or delivered on or after the date of the dispensing order (except for items that require written orders prior to delivery).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state “PRN” or “as needed” utilization estimates for replacement frequency, use, or consumption are not acceptable. (PIM 5.9)

The detailed description in the written order may be either a narrative description or a brand name/model number.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The DWO must be available upon request.

A prescription is not considered as part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record. (PIM 5.7)

NEW ORDER REQUIREMENTS (PIM 5.2.7)

A new prescription is required when:

- There is a change in the order for the accessory, supply, drug, etc.;
- On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy;
- When an item is replaced; and
- When there is a change in the supplier.

MEDICAL RECORD INFORMATION

GENERAL (PIM 5.7 - 5.9)

The COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY section of this LCD contains numerous reasonable and necessary (R&N) requirements. The NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

- Supplier-produced records, even if signed by the prescribing practitioner, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.
- Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.

Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to treating practitioner's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary.

PROOF OF DELIVERY (PIM 4.26, 5.8)

Proof of delivery (POD) is a Supplier Standard and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers are required to maintain POD documentation in their files. Regardless of the method of delivery, the contractor must be able to determine that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are received by a specific Medicare beneficiary.

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The signature and date the beneficiary or designee accepted delivery must be legible.

For the purpose of the delivery methods noted below, designee is defined as any person who can sign and accept the delivery of DMEPOS on behalf of the beneficiary.

Proof of delivery documentation must be available to the Medicare contractor on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently fail to provide documentation to support their services may be referred to the Office of Inspector General for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. There are two methods of delivery:

1. Delivery directly to the beneficiary or authorized representative

2. Delivery via shipping or delivery service

Method 1—Direct Delivery to the Beneficiary by the Supplier

Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery document. The POD document must include:

- Beneficiary's name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature

The date delivered on the POD must be the date that the DMEPOS item was received by the beneficiary or designee. The date of delivery may be entered by the beneficiary, designee or the supplier. When the supplier's delivery documents have both a supplier-entered date and a beneficiary or beneficiary's designee signature date on the POD document, the beneficiary or beneficiary's designee-entered date is the date of service.

In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply must be the date of service on the claim.

Method 2—Delivery via Shipping or Delivery Service Directly to a Beneficiary

If the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the beneficiary. An example of acceptable proof of delivery would include both the supplier's own detailed shipping invoice and the delivery service's tracking information. The supplier's record must be linked to the delivery service record by some clear method like the delivery service's package identification number or supplier's invoice number for the package sent to the beneficiary. The POD document must include:

- Beneficiary's name
- Delivery address
- Delivery service's package identification number, supplier invoice number or alternative method that links the supplier's delivery documents with the delivery service's records.
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a POD. This type of POD document must contain the information specified above.

This information must be available upon request.

CORRECT CODING (PIM 3.3)

Correct coding is a determination that the item(s) provided to the beneficiary are billed using the appropriate HCPCS code for the item. Suppliers are required to correctly code for the items billed. An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, or MAC articles. Information that is sufficiently detailed to unambiguously identify the specific product delivered to the beneficiary and the HCPCS code used to bill for that item must be maintained by the supplier and be available upon request.

For LCDs that use ICD-10 diagnosis codes, correct coding of the ICD-10 code is required. A diagnosis is correctly coded when it meets all the coding guidelines listed in International Classification of Diseases Guidelines (ICD), CMS ICD policy or guideline requirements, LCDs, or MAC articles. Information that is sufficiently detailed to unambiguously justify the ICD-10 code used to bill for DMEPOS items must be contained in the beneficiary's medical record and be available upon request.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

An order for each item billed must be signed and dated by the prescribing practitioner, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

If the prescribing practitioner is the supplier, a separate order is not required, but the item provided must be clearly noted in the beneficiary's record.

A new order is not required for the replacement of an insert or modification within one year of the order on file. However, the supplier's records should document the reason for the replacement. A new order is required for the replacement of any shoe. A new order is also required for the replacement of an insert or modification more than one year from the most recent order on file. The detailed written order must be signed on or after the date of the visit with the Prescribing Practitioner (see related Policy Article for information about the visit with the Prescribing Practitioner).

The supplier must obtain a signed statement from the practitioner who is managing the beneficiary’s systemic diabetes condition (i.e., the certifying physician) specifying that the beneficiary has diabetes mellitus, has one of conditions 2a-2f listed in the related Policy Article, is being treated under a comprehensive plan of care for his/her diabetes, and needs diabetic shoes. The certifying physician must be an M.D. or D.O and may not be a podiatrist, physician assistant, nurse practitioner, or clinical nurse specialist. The "Statement of Certifying Physician for Therapeutic Shoes" form (see LCD Attachments section below) is recommended. Whatever form is used must contain all of the elements contained on the recommended form attached to this LCD. This statement must be completed, signed, and dated by the certifying physician. A new Certification Statement is required for a shoe, insert or modification provided more than one year from the most recent Certification Statement on file.

There must be information in the medical records of the certifying physician that:

a. Documents management of the beneficiary’s diabetes; and
b. Documents detailed information about the condition (2a-2f listed in the related Policy Article) that qualifies the beneficiary for coverage.

The Certification Statement by itself does not meet this requirement for documentation in the medical records.

The in-person evaluation of the beneficiary by the supplier at the time of selecting the items that will be provided (refer to related Policy Article, Non-Medical Necessity Coverage and Payment Rules, criterion 4) must include at least the following:

1. An examination of the beneficiary’s feet with a description of the abnormalities that will need to be accommodated by the shoes/inserts/modifications.
2. For all shoes, taking measurements of the beneficiary’s feet.
3. For custom molded shoes (A5501) and inserts (A5513), taking impressions, making casts, or obtaining CAD-CAM images of the beneficiary’s feet that will be used in creating positive models of the feet.

The in-person evaluation of the beneficiary by the supplier at the time of delivery (refer to related Policy Article, Non-Medical Necessity Coverage and Payment Rules, criterion 5) must be conducted with the beneficiary wearing the shoes and inserts and must document that the shoes/inserts/modifications fit properly.

The diagnosis code that justifies the need for these items must be included on the claim.

KX, GA, GY AND GZ MODIFIERS:

Suppliers must add a KX modifier to codes for shoes, inserts, and modification only if criteria 1-5 in the Non-Medical Necessity Coverage and Payment Rules section of the related Policy Article have been met. This documentation must be available upon request. The Statement of Certifying Physician form is not sufficient to meet this requirement.

If criteria 1-5 in the Non-Medical Necessity Coverage and Payment Rules section of the related Policy Article have not been met, the GY modifier must be added to each code.

If a KX or appropriate GA, GY or GZ modifier is not included on the claim line, the claim line will be rejected as missing information.

Miscellaneous
Refer to the Supplier Manual for additional information on documentation requirements

Appendices
PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual 100-08

Utilization Guidelines
Refer to Coverage Indications, Limitations and/or Medical Necessity

Sources of Information and Basis for Decision
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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
07/01/2016	R4	Revision Effective Date 07/01/2016 DOCUMENTATION REQUIREMENTS: Revised: Standard documentation language for orders, added New order requirements, and Correct coding instructions; revised Proof of delivery instructions and removed Method 3 as it does not apply – Effective 04/28/16	• Provider Education/Guidance
07/01/2016	R3	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.	• Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R2	**Revision Effective Date: 10/31/2014** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to add who can enter date of delivery date on the POD Removed: ICD-9 CM reference	• Provider Education/Guidance
10/01/2015	R1	**Revision Effective Date: 02/04/2011 (June 2014 Publication)** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Detailed written order verbiage regarding reasonable and necessary denial (reference related policy article and PIM 5.2.3).	• Typographical Error

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Associated Documents

Attachments Statement of Certifying Physician (PDF - 10 KB)

Related Local Coverage Documents Article(s) A52501 - Therapeutic Shoes for Persons with Diabetes - Policy Article

Related National Coverage Documents N/A

Public Version(s) Updated on 09/29/2016 with effective dates 07/01/2016 - N/A Updated on 06/07/2016 with effective dates 07/01/2016 - N/A Updated on 04/17/2015 with effective dates 10/01/2015 - 06/30/2016 Updated on 06/12/2014 with effective dates 10/01/2015 - N/A Updated on 04/04/2014 with effective dates 10/01/2015 - N/A Back to Top

Keywords

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