



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 05/22/13
LAST REVIEW DATE: 09/04/18
LAST CRITERIA REVISION DATE: 09/04/18
ARCHIVE DATE:

INJECTABLE BULKING AGENTS FOR THE TREATMENT OF URINARY AND FECAL INCONTINENCE

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Bulking Agents (Urinary):

Bulking agents are endoscopically injected around the urethra or the ureter(s) to increase tissue bulk thereby increasing resistance to the outflow of urine. Types of bulking agents include:

- Calcium hydroxylapatite (Coaptite®)
- Durasphere® Carbon Coated Beads
- Polydimethylsiloxane (Macroplastique®)
- Teflon (Polytef® Paste)
- Zuidex™ Implacer™ System
- Autologous fat or autologous ear chondrocytes (Fat is harvested from the lower abdomen or chondrocytes are grown from a tissue biopsy of the individual's ear cartilage. Food and Drug Administration (FDA) approval is not required for autologous materials.)
- Autologous cellular therapy with fibroblasts, myoblasts, adipose-derived or muscle-derived stem cells

Bulking Agents (Fecal):

Perianal bulking agents have been investigated as a treatment for fecal incontinence. The bulking agent is injected into the submucosa of the anal canal to increase tissue bulk in the area, which narrows the opening of the anus. Perianal bulking agents include, *but are not limited to*:

- Durasphere®
- Gatekeeper
- Solesta®

Definitions:

Urgency-Frequency:

Uncontrollable urge to urinate that results in very frequent, small volumes.

Urinary Retention:

Inability to completely empty the bladder of urine.

Urinary Stress Incontinence:

Involuntary loss of urine from the urethra due to increased intra-abdominal pressure.

Urinary Urge Incontinence:

Leakage of urine when there is a strong urge to void.



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Definitions: (cont.)

Vesicoureteral Reflux (VUR):

Abnormal condition in which urine flows backward from the bladder to the kidneys. This condition causes recurrent urinary tract infections.

Grade I: Mild form and generally treated with antibiotics
Grade II – IV: Treated with bulking agents
Grade V: Treated with open surgery

Criteria:

For Deflux injectable gel for urinary disorders, see BCBSAZ Medical Coverage Guideline #0445, “*Urinary Disorder Treatments*”.

Urinary Incontinence:

Coaptite, Durasphere, and Macroplastique:

- Coaptite, Durasphere, or Macroplastique for the treatment of stress urinary incontinence is considered **medically necessary** for individuals who have failed appropriate conservative therapy.
- Coaptite, Durasphere, or Macroplastique for all other indications not previously listed is considered **experimental or investigational** based upon lack of final approval from the Food and Drug Administration.

These indications include, *but are not limited to:*

- Urge incontinence

Polytef Paste (Teflon):

- Polytef paste for the treatment of urinary incontinence is considered **experimental or investigational** based upon a lack of final approval from the Food and Drug Administration.

INJECTABLE BULKING AGENTS FOR THE TREATMENT OF URINARY AND FECAL INCONTINENCE (cont.)

Criteria: (cont.)

Urinary Incontinence: (cont.)

Zuidex Implacer System:

- Zuidex Implacer system is considered **experimental or investigational** based upon:
 1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

Autologous Fat and Ear Chondrocytes:

- Autologous fat or autologous ear chondrocytes for the treatment of urinary incontinence is considered **experimental or investigational** based upon a lack of scientific evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Autologous Cellular Therapy:

- Autologous cellular therapy, e.g., myoblasts, fibroblasts, muscle-derived stem cells, or adipose-derived stem cells, for the treatment of urinary incontinence is considered **experimental or investigational** based upon a lack of scientific evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Fecal Incontinence:

Injectable Perianal Bulking Agents:

- Injectable perianal bulking agents for the treatment of fecal incontinence are considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.



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Resources:

Literature reviewed 09/04/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 05/22/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.19 BCBS Association Medical Policy Reference Manual. Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence. Re-issue date 08/09/2018, issue date 12/01/1995.
2. La Torre F, de la Portilla F. Long-term efficacy of dextranomer in stabilized hyaluronic acid (NASHA/Dx) for treatment of faecal incontinence. *Colorectal Dis*. May 2013;15(5):569-574.
3. Lightner DJ, Fox J, Klingele C. Cystoscopic injections of dextranomer hyaluronic acid into proximal urethra for urethral incompetence: efficacy and adverse outcomes. *Urology*. Jun 2010;75(6):1310-1314.
4. Maeda Y, Laurberg S, Norton C. Perianal injectable bulking agents as treatment for faecal incontinence in adults. *Cochrane Database Syst Rev*. 2013;2:CD007959.
5. Sangster P, Morley R. Biomaterials in urinary incontinence and treatment of their complications. *Indian J Urol*. Apr 2010;26(2):221-229.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'ánii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulongan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalín, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

اگر شما، یا کسی که شما به او کمک میکنید، سوال در مورد Blue Cross Blue Shield of Arizona، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید].

Assyrian:

Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณกำลังช่วยเหลือถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิที่จะได้รับความช่วยเหลือและข้อมูลในภาษา ของคุณได้โดยไม่มีค่าใช้จ่าย โปรดขงหมายเลข โทร 877-475-4799