Coverage for the Shingles Vaccine Shingrix Established

Highmark Blue Cross Blue Shield has revised the coverage criteria for the Zoster shingles vaccine recombinant, adjuvanted (Shingrix). This Medical Policy will apply to both professional provider and facility claims. The effective date was February 12, 2018.

Coverage criteria added:

- Zoster (shingles vaccine recombinant, adjuvanted) – Shingrix - (Two doses age 50 years of age and older).

Please refer to Medical Policy I-8, Immunizations for additional information.
Coverage Criteria Revised for the Treatment of Gaucher Disease

Highmark Blue Cross Blue Shield has revised the coverage criteria for imiglucerase (Cerezyme), velaglucerase alfa (VPRIV) and taliglucerase alfa (Elelyso). This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Coverage criteria revised for imiglucerase (Cerezyme), velaglucerase alfa (VPRIV) and taliglucerase alfa (Elelyso):

- Anemia with hemoglobin less than or equal to 1.0 g/dL or more below the lower limit of normal for age and sex.
- Clinically significant hepatomegaly (liver size 1.25 or more times normal) or splenomegaly (spleen size 5 or more times normal).

Please refer to Medical Policy I-9, Treatment of Gaucher Disease for additional information.

Coverage Criteria Revised for Certolizumab (Cimzia)

Highmark Blue Cross Blue Shield has revised the coverage criteria for certolizumab (Cimzia®). This Medical Policy will apply to both professional provider and facility claims. The effective date was March 29, 2018.

Ustekinumab (Stelara) subcutaneous has been added as a preferred product in addition to adalimumab (Humira) for Crohn’s disease.

Please refer to Medical Policy I-27, Certolizumab (Cimzia) for additional information.
Coverage Criteria Established for Infliximab-qbtx (Ixifi)

Highmark Blue Cross Blue Shield has established coverage criteria for infliximab-qbtx (Ixifi). This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Infliximab-qbtx (Ixifi), an infliximab (Remicade) biosimilar, has been added to medical policy I-28 with the same coverage criteria as the current biosimilars on the policy.

Please refer to Medical Policy I-28, Infliximab for additional information.

Coverage Criteria Revised for Tocilizumab (Actemra)

Highmark Blue Cross Blue Shield has revised the coverage criteria for tocilizumab (Actemra®). This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Adalimumab (Humira) and etanercept (Enbrel) have been removed as preferred products for the treatment of polyarticular juvenile idiopathic arthritis.

Please refer to Medical Policy I-31, Tocilizumab (Actemra) for additional information.
Criteria Revised for Golimumab (Simponi, Simponi Aria)

Highmark Blue Cross Blue Shield has revised the coverage criteria for golimumab (Simponi®, Simponi Aria®). This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Coverage criteria added:

- Golimumab (Simponi Aria) IV injection may be considered medically necessary for the treatment of active psoriatic arthritis alone or in combination with methotrexate in adult patients.
- Golimumab (Simponi Aria) IV injection may be considered medically necessary for the treatment of adults with active ankylosing spondylitis.
- Golimumab (Simponi® Aria) IV is considered experimental/investigation and, therefore, non-covered when used in conjunction with another tumor necrosis factor blocker (e.g., Enbrel, Remicade, Humira, Kineret or Orencia).
- Golimumab (Simponi, Simponi Aria) is considered not medically necessary for an individual with any one of the following:
  - Tuberculosis or other active serious infections or a history of recurrent infections.
  - Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to rule out latent tuberculosis.
  - The patient tests positive for the hepatitis B virus.

Please refer to Medical Policy I-35, Golimumab (Simponi, Simponi Aria) for additional information.
**Coverage Criteria Revised for Ustekinumab (Stelara)**

Highmark Blue Cross Blue Shield has revised the coverage criteria for ustekinumab (Stelara®). This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Coverage criteria for ustekinumab (Stelara) intravenous (IV) for the treatment of Crohn’s disease has been revised to require that the individual has had an inadequate response or experienced intolerance with at least two (2) immunosuppressants or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker.

Please refer to Medical Policy I-37, Ustekinumab (Stelara) for additional information.

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**Criteria Revised for Agalsidase beta (Fabrazyme)**

Highmark Blue Cross Blue Shield has revised the coverage criteria for agalsidase beta (Fabrazyme®). This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Coverage criteria revised to include that agalsidase beta (Fabrazyme) is prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders.

Please refer to Medical Policy I-55, Agalsidase beta (Fabrazyme) for additional information.
Coverage Criteria Revised for Abatacept (Orencia)

Highmark Blue Cross Blue Shield has revised the coverage criteria for abatacept (Orencia®). This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Coverage criteria for abatacept (Orencia) subcutaneous (SC) injection for the treatment of juvenile idiopathic arthritis (JIA)/juvenile rheumatoid arthritis (JRA) has been revised to require treatment with at least one (1) preferred biologic product, adalimumab (Humira) or etanercept (Enbrel) has been ineffective or not tolerated, or both of these preferred products are contraindicated.

Abatacept (Orencia) SC may be considered medically necessary for the treatment of active psoriatic arthritis when the individual has a history of beneficial response to abatacept SC; or
- When all of the following are met:
  - Abatacept (Orencia) SC is to be used in the treatment of adults with active psoriatic arthritis.
  - Treatment with at least one (1) nonbiologic DMARD (e.g. methotrexate, leflunomide, sulfasalazin, hydroxychloroquine, or cyclosporine) was ineffective or not tolerated, or all nonbiologic DMARDs are contraindicated.
  - Treatment with at least two (2) of the following preferred products was ineffective or not tolerated, or all of these preferred products are contraindicated:
    - Adalimumab (Humira)
    - Etanercept (Enbrel)
    - Ustekinumab (Stelara)
    - Secukinumab (Cosentyx).

Please refer to Medical Policy I-90, Abatacept (Orencia) for additional information.
Coverage Criteria Revised for Cetuximab (Erbitux)

Highmark Blue Cross Blue Shield has revised the coverage criteria for cetuximab (Erbitux®) based on the National Comprehensive Cancer Network and the Food and Drug Administration approved indications. This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Please refer to Medical Policy I-100, Cetuximab (Erbitux) for additional information.

Coverage Criteria Revised for Treatment of Hereditary Angioedema (HAE)

Highmark Blue Cross Blue Shield has revised the coverage criteria for C1 esterase inhibitor [Human] (Cinryze), icatibant (Firazyr), ecallantide (Kalbitor), C-1 esterase inhibitor [Human] (Berinert) and C1 esterase inhibitor [recombinant] (Ruconest). This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Coverage criteria added:

- Medication is prescribed by an immunologist, allergist or rheumatologist.
- Not used in combination with other approved treatments for acute HAE attacks (e.g. Berinert, Firazyr, Kalbitor or Ruconest).

Coverage criteria revised:

- C1 esterase inhibitor [Human] (Cinryze): revised from greater than 13 years of age to greater than or equal to 9 years of age.
- C1 esterase inhibitor [human] (Berinert): revised from for all ages to greater than or equal to 5 years of age.
- C1 esterase inhibitor [recombinant] (Ruconest®) revised from greater than 12 years of age to greater than or equal to 13 years of age.

Please refer to Medical Policy I-122, Treatment of Hereditary Angioedema (HAE) for additional information.
Coverage Criteria Revised for Vedolizumab (Entyvio)

Highmark Blue Cross Blue Shield has revised the coverage criteria for vedolizumab (Entyvio®). This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Coverage criteria added:

- Infliximab-qbtx (Ixifi) added as an infliximab (Remicade) biosimilar.

Please refer to Medical Policy I-129, Vedolizumab (Entyvio) for additional information.

Coverage Criteria Revised for Obinutuzumab (Gazyva)

Highmark Blue Cross Blue Shield has revised the coverage criteria for obinutuzumab (Gazyva®) based on the National Comprehensive Cancer Network and the Food and Drug Administration approved indications. This Medical Policy will apply to both professional provider and facility claims. The effective date was February 26, 2018.

Please refer to Medical Policy I-137, Obinutuzumab (Gazyva) for additional information.

Coverage Position Established for GI Effects Comprehensive Stool Profile

Highmark Blue Cross Blue Shield has established a coverage position for GI Effects Comprehensive Stool Profile. This multianalyte stool assay is considered experimental/investigational for all indications, and therefore, non-covered. This will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Please refer to Medical Policy L-225, GI Effects Comprehensive Stool Profile, for additional information.
Coverage Criteria Revised for Assisted Reproductive Technology

Highmark Blue Cross Blue Shield has revised the coverage criteria for assisted reproductive technology. The title of medical policy U-5 has been revised from Assisted Fertilization to Assisted Reproductive Technology. This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Policy description has been revised to:

For the purpose of this policy infertility is defined as a condition (an interruption, cessation, or disorder of body functions, systems, or organs) of the reproductive tract which prevents the conception of a child or the ability to carry a pregnancy to delivery. This is evidenced by the failure to achieve a successful pregnancy after twelve (12) months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination. Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after six (6) months for women over age 35 years.

Artificial Insemination is a procedure, also known as intrauterine insemination (IUI) or intracervical/intravaginal insemination (ICI), by which sperm is directly deposited into the vagina, cervix or uterus to achieve fertilization and pregnancy.

Assisted Reproductive Technology includes all treatments or procedures that involve the in vitro (i.e., outside of the living body) handling of both human oocytes (eggs) and sperm, or embryos, for the purpose of establishing a pregnancy. Treatments and procedures include, but are not limited to, in vitro fertilization (IVF) and embryo transfer, gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), peritoneal ovum sperm transfer, zona drilling, sperm microinjection, gamete and embryo cryopreservation (freezing), oocyte and embryo donation, and gestational surrogacy or carrier, but does not include artificial insemination in which sperm are placed directly into the vagina, cervix or uterus.

Gestational surrogacy is an arrangement in which a woman carries and delivers a baby for another person or couple.

Coverage criteria added:

- Unexplained infertility and stage 4 endometriosis as defined by the American Society of Reproductive Medicine added as eligible additional risk factors for in vitro fertilization (IVF).
- Intracytoplasmic Sperm Injection (ICSI) may be considered medically necessary when the individual has diagnosed infertility due to a male factor, as defined by values based on the World Health Organization (WHO) semen-analysis criteria, demonstrated on at least two separate semen analyses.
- Medical services or supplies rendered to a gestational carrier or surrogate may be considered medically necessary if the member has any of the following indications:
  - Congenital absence of a uterus; or
  - Uterine anomalies that cannot be repaired; or
  - A medical condition for which pregnancy may pose a life-threatening risk.
- Payment for surrogate service fees for purposes of child birth is considered not medically necessary.

Coverage criteria removed:
• Severe endometriosis removed as a contraindication for IVF.
• Three (3) stimulated ovulation inductions removed as a requirement for IVF.
• Women who have at least one (1) healthy fallopian tube and those who aren’t suitable for gamete intrafallopian transfer (GIFT) or embryo transfer through the vagina (transvaginal procedure) removed as a requirement for Tubal embryo transfer (TET).

Please refer to Medical Policy U-5, Assisted Reproductive Technology for additional information.

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**Revised Criteria for Transcranial Magnetic Stimulation (TMS)**

Highmark Blue Cross Blue Shield has revised Transcranial Magnetic Stimulation (TMS) criteria for Alzheimer’s disease. This will apply to both professional provider and facility claims. The effective date is May 28, 2018.

TMS of the brain is considered experimental/investigational and therefore, non-covered for any other indication, including, but not limited to Alzheimer’s disease. There is insufficient evidence in the published peer-reviewed literature to support the effectiveness of this procedure.

Please refer to Medical Policy Z-4, Transcranial Magnetic Stimulation (TMS), for additional information.

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**Coverage Criteria Revised for Hyaluronan Injections for Osteoarthritis of the Knee**

Highmark Blue Cross Blue Shield has revised the criteria for intra-articular hyaluronan injections for osteoarthritis of the knee. Durolane (hyaluronic acid), Supartz (sodium hyaluronate), and GelSyn-3 (hyaluronic acid) will be considered preferred injections and Euflexxa (sodium hyaluronate) will remain a preferred injection. Synvisc and Synvisc-One (hylan G-F 20) will be considered non-preferred injections. This Medical Policy will apply to both professional provider and facility claims. The effective date is June 1, 2018.

Please refer to Medical Policy G-25, Intra-Articular Hyaluronan Injections for Osteoarthritis of the Knee for additional information.
Policy Coverage Update Team Surgery

Highmark Blue Cross Blue Shield has revised the coverage criteria for team surgery eligibility. This revision will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Revisions to this policy are based on the following:
- Coverage for eligible services for team surgery will be applied to this policy based on the Medicare Physician's Fee Schedule Database (MPFS).
- Services with a team surgery indicator of a “2” will be added.
- Indicators 0, 1 and 9 are considered not medically necessary.

Team Surgery Payment Indicator Chart:

| 0 | Team surgeons are not permitted for this procedure. |
| 1 | Team surgeons may be allowed with supporting documentation. |
| 2 | Team surgeons permitted. |
| 9 | Team surgery concept does not apply. |

Refer to Medical Policy S-12, Team Surgery for additional information.

Policy Coverage Update Assistant Surgery Eligibility Criteria

Highmark Blue Cross Blue Shield has revised the coverage criteria for assistant surgery eligibility. This revision will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Revisions to this policy are based on the following:
- Coverage for eligible services for assistant surgery will be applied to this policy based on the Medicare Physician's Fee Schedule Database (MPFS).
- Services with an assistant surgery indicator of a “2” will be added.
- Indicators 0, 1 and 9 are considered not medically necessary.

Assistant Surgery Payment Indicator Chart:

| 0 | Payment restriction for assistants at surgery applies to this procedure unless supporting documentation is submitted to establish medical necessity. |
| 1 | Statutory payment restriction for assistants at surgery applies to this procedure. Assistant at surgery may not be paid. |
| 2 | Payment restriction for assistants at surgery does not apply to this procedure. Assistant at surgery may be paid |
| 9 | Assistant at surgery concept does not apply |

Refer to Medical Policy S-16, Assistant Surgery Eligibility Criteria for additional information.
Policy Coverage Update Co-Surgery

Highmark Blue Cross Blue Shield has revised the coverage criteria for co-surgery surgery eligibility. This revision will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Revisions to this policy are based on the following:

- Coverage for eligible services for assistant surgery will be applied to this policy based on the Medicare Physician's Fee Schedule Database (MPFS).
- Services with an assistant surgery indicator of a “2” will be added.
- Indicators 0, 1 and 9 are considered not medically necessary.

Co-Surgery Payment Indicator Chart:

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Co-surgeons are not permitted for this procedure.</td>
</tr>
<tr>
<td>1</td>
<td>Co-surgeons may be allowed with supporting documentation.</td>
</tr>
<tr>
<td>2</td>
<td>Co-surgeons are permitted without submission of documentation if the two-specialty requirement is met.</td>
</tr>
<tr>
<td>9</td>
<td>Co-surgery concept does not apply.</td>
</tr>
</tbody>
</table>

Refer to Medical Policy S-112, Co-Surgery for additional information.

Coverage Guidelines Revised for Recombinant Platelet-Derived Growth Factors

Highmark Blue Cross Blue Shield has revised the coverage guidelines for Recombinant Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions. These revised guidelines will apply to both professional provider and facility claims. The effective date is July 2, 2018.

Recombinant platelet-derived growth factor (i.e., becaplermin [Regranex]) may be considered medically necessary when used as an adjunct to standard wound management when EITHER of the following criteria has been met:

- Neuropathic diabetic ulcers extending into the subcutaneous tissue or beyond and have an adequate blood supply; or
- Pressure ulcers extending into the subcutaneous tissue.

Please refer to Medical Policy S-180, Recombinant and Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions, for additional information.
Coverage Criteria Established for Tocilizumab (Actemra)

Highmark’s Medicare Advantage products have established coverage criteria for tocilizumab (Actemra®) based on the National Comprehensive Cancer Network and the Food and Drug Administration approved indications. This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Please refer to Medical Policy I-31, Tocilizumab (Actemra) for additional information.

Coverage Criteria Established for Belimumab (Benlysta)

Highmark’s Medicare Advantage products have established coverage criteria for belimumab (Benlysta®) based on the Food and Drug Administration approved indications. This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Please refer to Medical Policy I-33, Belimumab (Benlysta) for additional information.

Coverage Criteria Revised for Cetuximab (Erbitux)

Highmark’s Medicare Advantage products have revised the coverage criteria for cetuximab (Erbitux®) based on the National Comprehensive Cancer Network and the Food and Drug Administration approved indications. This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Please refer to Medical Policy I-69, Cetuximab (Erbitux) for additional information.
Coverage Criteria Revised for Obinutuzumab (Gazyva)

Highmark’s Medicare Advantage products have revised the coverage criteria for obinutuzumab (Gazyva®) based on the National Comprehensive Cancer Network and the Food and Drug Administration approved indications. This Medical Policy will apply to both professional provider and facility claims. The effective date was February 26, 2018.

Please refer to Medical Policy I-137, Obinutuzumab (Gazyva) for additional information.

Coverage Criteria Established for Certolizumab (Cimzia)

Highmark’s Medicare Advantage products have established coverage criteria for certolizumab (Cimzia®) based on the Food and Drug Administration approved indications. This Medical Policy will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Please refer to Medical Policy I-184, Certolizumab (Cimzia) for additional information.
New Policy Established for AlloSure Donor-Derived Cell-Free DNA Test

Highmark's Medicare Advantage product has established new coverage guidelines for AlloSure® test. This new Medicare Advantage Medical Policy will apply to both professional provider and facility claims. The effective date is February 26, 2018.


Policy Coverage Update Team Surgery

Highmark’s Medicare Advantage products have revised the coverage criteria for team surgery eligibility. This revision will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Revisions to this policy are based on the following:

• Coverage for eligible services for team surgery will be applied to this policy based on the Medicare Physician's Fee Schedule Database (MPFS).
• Services with a team surgery indicator of a “2” will be added.
• Indicators 0, 1 and 9 are considered not medically necessary.

Team Surgery Payment Indicator Chart:

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<td>1</td>
<td>Team surgeons may be allowed with supporting documentation.</td>
</tr>
<tr>
<td>2</td>
<td>Team surgeons permitted.</td>
</tr>
<tr>
<td>9</td>
<td>Team surgery concept does not apply.</td>
</tr>
</tbody>
</table>

Refer to Medicare Advantage Medical Policy N-120, Team Surgery, for additional information.
Policy Coverage Update Co-Surgery

Highmark’s Medicare Advantage products have revised the coverage criteria for co-surgery eligibility. This revision will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Revisions to this policy are based on the following:
- Coverage for eligible services for assistant surgery will be applied to this policy based on the Medicare Physician’s Fee Schedule Database (MPFS).
- Services with an assistant surgery indicator of a “2” will be added.
- Indicators 0, 1 and 9 are considered not medically necessary.

Co-Surgery Payment Indicator Chart:

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<td>2</td>
<td>Co-surgeons are permitted without submission of documentation if the two-specialty requirement is met.</td>
</tr>
<tr>
<td>9</td>
<td>Co-surgery concept does not apply.</td>
</tr>
</tbody>
</table>

Refer to Medicare Advantage Medical Policy N-112, Co-Surgery, for additional information.

Policy Coverage Update Assistant at Surgery Services

Highmark’s Medicare Advantage products have revised the coverage criteria for assistant surgery eligibility. This revision will apply to both professional provider and facility claims. The effective date is May 28, 2018.

Revisions to this policy are based on the following:
- Coverage for eligible services for assistant surgery will be applied to this policy based on the Medicare Physician’s Fee Schedule Database (MPFS).
- Services with an assistant surgery indicator of a “2” will be added.
- Indicators 0, 1 and 9 are considered not medically necessary.

Assistant at Surgery Payment Indicator Chart:

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Payment restriction for assistants at surgery applies to this procedure unless supporting documentation is submitted to establish medical necessity.</td>
</tr>
<tr>
<td>1</td>
<td>Statutory payment restriction for assistants at surgery applies to this procedure. Assistant at surgery may not be paid.</td>
</tr>
<tr>
<td>2</td>
<td>Payment restriction for assistants at surgery does not apply to this procedure. Assistant at surgery may be paid</td>
</tr>
<tr>
<td>9</td>
<td>Assistant at surgery concept does not apply</td>
</tr>
</tbody>
</table>

Refer to Medicare Advantage Medical Policy N-28, Assistant at Surgery Services for additional information.
Comments on these new medical policies?
We want to know what you think about our new medical policy changes. Send us an email with any questions or comments that you may have on the new medical policies in this edition of Medical Policy Update.

Write to us at medicalpolicy@highmark.com.

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For inquiries about eligibility, benefits, claim status or authorizations, Highmark Blue Cross Blue Shield encourages providers to use the electronic resources available to them - Navinet® and the applicable HIPAA transactions – prior to placing a telephone call to the Provider Service Center at 1-800-242-0514.

Acknowledgement
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