The Blue Cross and Blue Shield of Nebraska (BCBSNE) Medical Policy Committee (MPC) is composed of practicing physicians within the BCBSNE network. The committee utilizes contract criteria summarized online at [www.nebraskablue.com](http://www.nebraskablue.com) to determine whether a new technology or new application of an existing technology is scientifically valid or investigative.

At the 2013 third quarter meeting, the following decisions were made:

<table>
<thead>
<tr>
<th>Medical Policy</th>
<th>Revision</th>
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<tbody>
<tr>
<td><strong>Sequencing-based tests to determine trisomy 13, 18, and 21 from maternal plasma</strong></td>
<td><strong>New Policy.</strong> Testing is Scientifically Validated in women with high-risk singleton pregnancies.</td>
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<tr>
<td>High risk guidelines:</td>
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<tr>
<td>• Maternal age 35 years or older at delivery;</td>
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<td>• Fetal ultrasonographic findings indicating increased risk of aneuploidy;</td>
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<tr>
<td>• History of previous pregnancy with a trisomy;</td>
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<tr>
<td>• Standard serum screening test positive for aneuploidy; or</td>
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<tr>
<td>• Parental balanced robertsonian translocation with increased risk of fetal trisomy 13 or trisomy 21.</td>
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<td></td>
<td>All other uses are Investigative.</td>
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<tr>
<td><strong>Notification given:</strong> 09/26/2013</td>
<td><strong>Effective date:</strong> 12/26/2013</td>
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</tbody>
</table>

| **Policy III.109 Heart-Assist Devices/Ventricular Assist Device** | **Addition.** Total artificial heart is Scientifically Validated as a bridge to heart transplantation for patients with biventricular failure who have no other reasonable medical or surgical treatment options, who are ineligible for other univentricular or biventricular support devices, and are currently listed as heart transplant candidates or are undergoing evaluation to determine candidacy for heart transplantation, and not expected to survive until a donor heart can be obtained. All other uses are Investigative. |
|                                                               | Policy title will be changed to: **Ventricular Assist Devices and Total Artificial Hearts** |
| **Notification given:** 09/26/2013                                             | **Effective date:** 12/26/2013                                           |
Policy I.155
Outpatient Cardiac Telemetry

Addition. The use of a patient-activated or auto-activated external ambulatory event monitor (AEM or loop recorder) (CPT codes 93268, 93270, 93271, 93272) may be considered Medically Necessary as a diagnostic alternative to the use of a 24- to 48-hour continuous external unattended cardiac monitoring device (e.g., Holter monitor) in:

- Patients who experience recurrent but infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, pre-syncope, or syncope) OR
- Patients with atrial fibrillation who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered, and whose CHADS score is ≤ 1

The use of an implantable loop recorder (CPT codes 33282, 33284, 93285, 93291, 93297, 93298, 93299, and HCPCS codes C1764, E0616), either patient-activated or auto-activated may be Medically Necessary for the evaluation of recurrent, unexplained episodes of syncope/pre-syncope suspected to be of cardiac origin only in the small subset of those patients who experience recurrent symptoms so infrequently that a prior trial of Holter monitor and other external ambulatory event monitors has been unsuccessful AND when ALL of the following criteria are met:

- Patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, pre-syncope, or syncope) AND
- Non-invasive ambulatory monitoring (e.g., Holter, external AEMs) failed to establish a definitive diagnosis because the symptoms occur so infrequently and unpredictably that the length of the monitoring period may have been inadequate to capture a diagnostic electrocardiogram (ECG) rhythm disorder.

The use of continuous monitoring devices with longer recording times (The Zio® Patch) (CPT codes 0295T, 0296T, 0297T, 0298T) may be considered Medically Necessary as an alternative to an Implantable Loop Recorder for patients who meet ALL of the criteria for an implantable loop recorder (see above guidelines).

All other uses of ambulatory event monitors and telemetry are Investigative, including, but not limited to, the following clinical situations:

- Monitoring effectiveness of anti-arrhythmia therapy and detection of myocardial ischemia by detecting ST segment changes;
- Following catheter or surgical ablation of atrial fibrillation;
- Monitoring for the presence of atrial fibrillation in individuals with cryptogenic stroke.

Policy title will be changed to: Cardiac Events Monitors and Outpatient Cardiac Telemetry

Notification date: 09/26/2013
Effective date: 10/01/2013
**New Policy.** IVIG is Scientifically Validated for the following indications:

**Primary immune deficiency syndromes, including combined immunodeficiencies**

- X-linked agammaglobulinemia (Bruton’s) X-linked hyper-IgM syndrome
- Severe Combined Immunodeficiency (SCID)
- Wiskott-Aldrich syndrome
- Ataxia telangiectasia
- Patients with primary immunodeficiency syndromes should meet all the following criteria for treatment with immune globulin:
  - Laboratory evidence of immunoglobulin deficiency (see Policy Guidelines)
  - Documented inability to mount an adequate immunologic response to inciting antigens (see Policy Guidelines)
  - Persistent and severe infections despite treatment with prophylactic antibiotics

**Acute Humoral Rejection**

**Autoimmune Mucocutaneous Blistering Diseases**, in patients with severe, progressive disease despite treatment with conventional agents (corticosteroids, azathioprine, cyclophosphamide, etc.)

- Pemphigus
- Pemphigoid
- Pemphigus vulgaris
- Pemphigus foliaceus
- Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN)

**Autoimmune and Inflammatory Disorders**

- Dermatomyositis refractory to treatment with corticosteroids; in combination with other immunosuppressive agents
- Kawasaki syndrome*

**Neuroimmunological**

- Myasthenia gravis in patients with chronic debilitating disease in spite of treatment with cholinesterase inhibitors, or complications from or failure of corticosteroids and/or azathioprine.
- Myasthenia crisis (i.e., an acute episode of respiratory muscle weakness) in patients with contraindications to plasma exchange
- Guillain-Barre syndrome
- Chronic inflammatory demyelinating polyneuropathy (CIDP)*; in patients with progressive symptoms for at least two months
- Multifocal motor neuropathy
- Eaton-Lambert myasthenic syndrome; in patients who have failed to respond to anticholinesterase medications and/or

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corticosteroids.

Hematologic

- Idiopathic thrombocytopenic purpura (ITP)
  - Treatment of acute, severe ITP (see policy guidelines)
  - Treatment of chronic ITP*; in patients with at least 6 months’ duration of disease, and with persistent thrombocytopenia despite treatment with corticosteroids and splenectomy
- Neonatal alloimmune thrombocytopenia;
- Allogeneic post-bone marrow transplant setting
- B cell chronic lymphocytic leukemia (CLL); in patients with hypogammaglobulinemia and persistent bacterial infections
- Warm antibody autoimmune hemolytic anemia, refractory to corticosteroids and immunosuppressive agents
- Anti-phospholipid syndrome
- Severe anemia due to parvovirus B19

Infectious Diseases

- HIV [human immunodeficiency virus]-infected patients
- Toxic shock syndrome
- Patients with primary defective antibody synthesis

Transplantation

- Prior to solid organ transplant, treatment of patients at high risk of antibody-mediated rejection, including highly sensitized patients and those receiving an ABO incompatible organ.
- Following solid-organ transplant, treatment of antibody-mediated rejection

Multiple Sclerosis

IVIG is Scientifically Validated as an off-label indication for patients with relapsing-remitting Multiple Sclerosis with documented treatment failure, contraindication, or intolerance to available standard immunomodulatory therapy (e.g. interferon therapy).

Other applications of IVIG therapy are considered Investigative, including, but not limited to, the following conditions:

- Chronic progressive multiple sclerosis;
- Refractory rheumatoid arthritis and other connective tissue diseases, including systemic lupus erythematosus;
- Recurrent spontaneous abortion (see below for related laboratory tests);
- Inclusion-body myositis; polymyositis, including refractory polymyositis;
• Myasthenia gravis in patients responsive to immunosuppressive treatment;
• Other vasculitides besides Kawasaki disease, including vasculitis associated with anti-neutrophil cytoplasmic antibodies (ANCA; e.g., Wegener’s granulomatosis, polyarteritis nodosa), Goodpasture’s syndrome, and vasculitis associated with other connective tissue diseases;
• Thrombotic thrombocytopenic purpura;
• Hemolytic uremic syndrome;
• Paraneoplastic syndromes, other than Eaton-Lambert myasthenic syndrome
• Demyelinating polyneuropathy associated with IgM paraproteinemia;
• Epilepsy;
• Chronic sinusitis;
• Asthma;
• Chronic fatigue syndrome;
• Aplastic anemia;
• Diamond-Blackfan anemia;
• Red cell aplasia;
• Acquired factor VIII inhibitors;
• Hemophagocytic syndrome;
• Acute lymphoblastic leukemia;
• Multiple myeloma;
• Immune-mediated neutropenia;
• Nonimmune thrombocytopenia;
• Cystic fibrosis;
• Recurrent otitis media;
• Diabetes mellitus;
• Behcet’s syndrome;
• Adrenoleukodystrophy; stiff person syndrome;
• Organ transplant rejection;
• Uveitis;
• Demyelinating optic neuritis;
• Recent-onset dilated cardiomyopathy;
• Fisher syndrome;
• Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS);
• Autism;
• Complex regional pain syndrome;
• Alzheimer’s disease;
• IGG sub-class deficiency;
• Sepsis including neonatal sepsis;
• Crohn’s disease;
• Opsoclonus-myoclonus;
• Birdshot retinopathy;
• Epidermolysis bullosa acquisita;
• Necrotizing fasciitis;
• Polyradiculoneuropathy (other than CIDP).
### Subcutaneous Immune Globulin (SC Ig) Therapy

SC Ig may be considered **medically necessary** for the treatment of primary immunodeficiencies*, including congenital agammaglobulinemia, hypogammaglobulinemia, common variable immunodeficiency (CVID), severe combined immunodeficiency, Wiskott-Aldrich syndrome, and X-linked agammaglobulinemia (XLA).

**Notification given:** 09/26/2013  
**Effective date:** 01/01/2014

| Policy V.15 Genetic Testing for Non-Cancerous Inheritable Disease | Updated Policy.  
**Effective date:** 07/23/2013 |
| --- | --- |
| Policy V.16 Genetic Testing for Cancer Susceptibility | Updated Policy.  
**Effective date:** 07/23/2013 |
| **BRCA testing** | We will be adding the BRCA testing criteria to policy V.16.  
Genetic testing for inherited BRCA1 or BRCA2 mutations is Scientifically Validated in: |
|  | • Individuals who have breast or ovarian cancer; **OR**  
• Individuals who have first degree relatives with breast or ovarian cancer; **OR**  
• Individuals who have family members with known BRCA1 or BRCA2 mutations; **OR**  
• Unaffected individuals from families with a high risk of BRCA1 or BRCA2 mutation based on a family history, where it is not possible to test an affected family member for a mutation. |
|  | **Notification given:** 09/26/2013  
**Effective date:** 12/26/2013 |
| Policy X.11 Trastuzumab/Herceptin and Pertuzumab/Perjeta | **Policy title change.** Drugs to treat cancers which over express HER 2 protein. |
| Policy X.31 Interferon for Multiple Sclerosis | **Policy title change.** Disease modifying therapies for Multiple Sclerosis. |
References updated with no changes to the Policy Statements:
III.125  Monitoring of Sensory Evoked Potentials
III.142  Percutaneous Disc Procedures
III.158  Total Ankle Replacement
III.172  Intrastromal Corneal Ring Segments
III.175  Lung Reduction Surgery
III.178  Bronchial Thermoplasty
IV.51   Ophthalmologic Techniques for Glaucoma
IV.73   Assessment of Subclinical Atherosclerosis
VII.15  CPM
VII.49  Sensory Integration Therapy
VII.51  Continuous Monitoring of Glucose in the Interstitial Fluid