Medical Policy updates

The following applies to Blue Care Network members:

- Noncovered services appear first; covered services follow.
- The effective date is indicated for the service, technology or procedure.

Noncovered services

Gene expression profiling for uveal melanoma

- New policy
- Effective date: Sept. 1, 2015
- Procedure codes: *81599, *84999

Uveal melanoma, although rare, is the most common primary intraocular malignancy in adults. Metastatic disease is the leading cause of death in patients with uveal melanoma, and approximately 50 percent of patients will develop distant metastasis.

Genetic analysis of uveal melanoma can provide prognostic information for the risk of developing metastatic disease. Gene expression profiling has been proposed as a method to stratify patients into prognostic risk groups. One such test, DecisionDx-UM®, is a gene expression profiling test intended to assess five-year metastatic risk in uveal melanoma. The test claims to identify a tumor’s likelihood of metastasis within five years.

Studies suggest that gene expression profiling may be able to accurately predict which patients with uveal melanoma are at greatest risk for developing metastasis. However, there appears to be no incremental benefit in its use over currently established prognostic clinical markers for predicting the risk of metastases, nor is there evidence that use of the test will change clinical management or alter treatment decisions that will lead to improved clinical outcomes.

Gene expression profiling for uveal melanoma has been determined to be experimental. Peer-reviewed literature hasn’t demonstrated the clinical utility of this service.

Genetic testing for mental health conditions using testing panels

- New policy
- Effective date: Sept. 1, 2015

Psychiatric disorders cover a wide range of clinical phenotypes and are generally classified by symptomatology in systems such as the classification outlined in the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). In addition to counseling and other forms of behavioral treatment, treatment commonly involves one or more psychotropic medications aimed at alleviating symptoms of the disorder. Although there are a wide variety of effective medications, treatment of psychiatric disease is characterized by relatively high rates of inadequate response. This often necessitates numerous trials of individual agents and combinations of medications to achieve optimal response.

Several commercially available testing panels include genes related to neurotransmitter function and pharmacokinetics of psychiatric drugs. They are intended to be an aid in clinical decision making regarding interventions for psychiatric conditions. The peer-reviewed medical literature hasn’t yet demonstrated the clinical utility of genetic testing for mutations associated with mental health disorders.

Genetic testing for mutations associated with mental health disorders is considered experimental in all situations, including but not limited to the following:

- To confirm a diagnosis of a mental health disorder in an affected individual
- To predict future risk of a mental health disorder in an asymptomatic individual
- In an affected individual, to inform the selection or dose of medications used to treat mental health disorders

Cont.
Leadless permanent cardiac pacemakers

- New policy
- Effective date: Sept. 1, 2015

A leadless cardiac pacemaker system is comprised of a pulse generator with built-in battery and electrode for implantation in a cardiac chamber via a transfemoral catheter approach. These pacemakers are designed to achieve the same pacing results as a standard pacemaker, but the process for implantation is different from standard pacemakers. The leadless pacemaker is placed via a catheter into the right ventricle. Unlike a standard pacemaker, a leadless pacemaker doesn’t require creation of a surgical pocket for the pacemaker and it requires no leads. The pacemaker battery life is equivalent to that of similar standard single chamber pacemakers. A number of leadless cardiac pacemakers are currently in development, including the Nanostim™ Leadless Pacemaker (St. Jude Medical) and the Micra™ Transcatheter Pacing System by Medtronic. However, there are no leadless cardiac pacemakers that have received approval from the Food and Drug Administration at this time.

The leadless permanent cardiac pacemakers are experimental. There is insufficient evidence in published, peer-reviewed medical literature regarding the safety and efficacy of these devices, and they are currently not FDA-approved. They haven’t been scientifically demonstrated to improve patient clinical outcomes.

Multi-biomarker disease activity (MBDA) laboratory testing (e.g., Vectra DA blood test) for rheumatoid arthritis

- New policy
- Effective date: Jan. 1, 2015
- Procedure code: *84999

Rheumatoid arthritis, or RA, is a disorder characterized by chronic joint inflammation leading to painful symptoms, progressive joint destruction and loss of function. The focus of treating RA has become more proactive, focusing on maintaining a tight control of RA and its symptoms with the goal of delaying disease progression by using disease modifying anti-rheumatic drugs.

There are numerous disease activity measurements that can be used to ensure that there is tight control of the progression of the disease. They include both subjective and objective measurements. A new test, Vectra DA, measures levels of 12 individual serum biomarkers. An algorithm is then applied to these measurements to calculate a single Vectra DA score ranging from one to 100 categorizing rheumatoid arthritis into low, moderate or high disease activity. It is proposed that the Vectra DA test can provide a baseline assessment of RA disease activity in adults diagnosed with RA and track it over time.

A small number of studies evaluated the clinical utility of the Vectra DA test by examining changes in decision-making associated with use of this test. These study designs are limited by the use of simulated cases or physician surveys and the lack of reported outcomes data.

The Vectra DA test is considered experimental for use as a measure of disease activity in the patients with RA. The limited body of evidence on the Vectra DA test is insufficient to determine whether it is as good as or better than other disease activity measures.

Cont.
Medical Policy updates

Cont.

**Covered services**

**JAK2 and MPL mutation analysis in myeloproliferative neoplasms**

- New policy
- Effective date: Sept. 1, 2015
- Requires clinical review; use contracted laboratory vendor
- Procedure codes: *81270, *81403, *81402

Diagnosis of the various classic forms of myeloproliferative neoplasms, or MPNs, is based on a complex set of clinical, pathological and biological criteria first introduced by the Polycythemia Vera Study Group in 1996 or by the World Health Organization in 2001 (updated 2008). Both classifications use a combination of clinical, pathological and biological criteria to reach definitive diagnoses. An important component of the diagnostic process is a clinical and laboratory assessment to rule out reactive or secondary causes of disease.

Mutations in the gene encoding Janus kinase 2 protein, known as JAK2, and in the myeloproliferative leukemia virus oncogene encoding the thrombopoietin receptor are associated with MPNs and with acute lymphoblastic leukemia in Down syndrome patients.

Although these mutations were of importance in better understanding the biology of MPNs, they also were of immediate interest as laboratory tools to aid in diagnosis and management of disease. At least four potential intended uses for mutation testing are considered, including:

a) Diagnosis of patients with clinical, laboratory, or pathologic findings suggesting classic MPNs (polycythemia vera, essential thrombocytopenia or primary myelofibrosis)

b) Diagnosis or selection of treatment for patients with Down syndrome and acute lymphoblastic leukemia

c) Phenotyping of disease subtypes in patients with MPNs to establish disease prognosis

d) Identification, selection and monitoring of treatment

The safety and effectiveness of JAK2 tyrosine kinase and myeloproliferative leukemia virus mutation testing are established. It may be considered a useful diagnostic option for patients presenting with clinical, laboratory or pathologic findings suggesting classic forms of MPNs, that is polycythemia vera, essential thrombocytopenia or primary myelofibrosis.

JAK2 tyrosine kinase and myeloproliferative leukemia virus mutation testing is experimental in all other circumstances including, but not limited to, the following:

- Diagnosis of nonclassic forms of myeloproliferative neoplasms
- Molecular phenotyping of patients with myeloproliferative neoplasms
- Monitoring, management, or selecting treatment in patients with myeloproliferative neoplasm
- Diagnosis or selection of treatment in patients with Down syndrome and acute lymphoblastic leukemia

* CPT codes, descriptions and two-digit numeric modifiers only are copyright 2014 American Medical Association. All rights reserved.
Medical Policy updates

Cont.

MRI guided focused ultrasound

- Revised policy
- Effective date: Sept. 1, 2015
- Plan notification/referral required (unlisted procedure code requires clinical review)
- Procedure codes: *0071T, *0072T, *76999

MRI guided focused ultrasound is a noninvasive treatment that combines two technologies, focused ultrasound and magnetic resonance imaging. The ultrasound beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. The ultrasound causes a local temperature increase in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. The ultrasound waves from each sonication are focused at a focal point that has a maximum focal volume of 20 nm in diameter and 15 nm in height/length. This causes a rapid rise in temperature (to approximately 65-85°C), which is sufficient to achieve tissue ablation at the focal point. In addition to providing guidance, the associated MRI can provide online thermometric imaging that provides a temperature “map” that can further confirm the therapeutic effect of the ablation treatment and allow for real-time adjustment of the treatment parameters.

The safety and effectiveness of magnetic resonance imaging guided high-intensity ultrasound ablation is established. It may be a considered a useful therapeutic option for pain relief in adult patients with metastatic bone cancer who failed or aren’t candidates for radiotherapy.

MRI guided focused ultrasound isn’t covered in all other situations including but not limited to:

- Treatment of uterine fibroids
- Treatment of other tumors such as brain cancer, prostate cancer and breast cancer

Genetic testing for epilepsy

- Revised policy
- Requires clinical review; use contracted laboratory vendor
- Effective date: Sept. 1, 2015

Epilepsy is a disorder characterized by unprovoked seizures. It’s a heterogenous condition that encompasses many different types of seizures that vary in age of onset and severity. The common epilepsies, also called idiopathic epilepsy, are thought to have a complex, multifactorial genetic basis. There are numerous rare epileptic syndromes that occur in infancy or early childhood which may be caused by a single gene mutation. Genetic testing is commercially available for a large number of genetic mutations that may be related to epilepsy.

Genetic testing of individuals with infantile and early childhood onset epilepsy syndromes in which epilepsy is the core clinical symptom may be considered established if positive test results may lead to changes in (must meet one of the following):

- Medication management
- Diagnostic testing such that alternative potentially invasive tests are avoided
- Reproductive decision-making

Genetic testing for infantile and early childhood onset epilepsy syndromes is safe and effective as a diagnostic option for patients meeting criteria. It hasn’t been proven to be a therapeutic option for other epilepsy conditions.
Noninvasive techniques for the evaluation and monitoring of patients with chronic liver disease

- New policy
- Effective date: Jan. 1, 2015
- No referral required
- Procedure code: *91200

The diagnosis of non-neoplastic liver disease is often made from needle biopsy samples. In addition to establishing a disease etiology, liver biopsy can determine the degree of inflammation present and can stage the degree of fibrosis. Noninvasive imaging technologies including transient elastography, acoustic radiation force impulse imaging, magnetic resonance elastography and real-time tissue elastography are alternatives to liver biopsy to detect liver fibrosis or cirrhosis among patients with chronic liver disease.

Clinical literature supports the accuracy and utility of transient elastography for evaluating and monitoring tissue fibrosis in chronic liver disease. However, the effectiveness of transient elastography is unreliable in patients who have ascites or a body mass index >30kg/m². The literature on acoustic radiation force impulse imaging, magnetic resonance elastography and real-time tissue elastography is limited and therefore no conclusions can be drawn as to the role of these imaging modalities in current clinical practice.

The safety and effectiveness of transient elastography for the evaluation and/or monitoring of patients with chronic liver disease are established. It may be considered a useful diagnostic option when indicated.

The use of other noninvasive imaging, including but not limited to magnetic resonance elastography, acoustic radiation force impulse imaging or real-time tissue elastography, is considered experimental for the evaluation and monitoring of patients with chronic liver disease. While these services may be safe, their clinical utility in this clinical indication hasn’t been determined.
Prostatic urethral lift procedure for the treatment of benign prostatic hypertrophy

- New policy
- Effective date: Sept. 1, 2015
- Requires clinical review
- Procedure codes: *52441, *52442

A new procedure has been developed for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hypertrophy, or BPH. It is called the prostatic urethral lift procedure. It may also be referred to as the Prostatic UroLift, UroLift system or the transprostatic implant system. The manufacturer, NeoTract, Inc., has developed a system for retracing the prostate tissue away from the urethra without cutting, heating or removing the prostate tissue. This technique is proposed as an alternative for men who are poor candidates for more invasive procedures.

This procedure consists of inserting small, permanent transprostatic implants placed cystoscopically to compress the prostate tissue, therefore increasing the urethral lumen and reducing obstruction to urine flow. Subsequently, four or five implants are delivered into the prostatic urethra to maintain urethral patency. The implants pull the prostate tissue away from the urethra, resulting in a stronger urine flow. A final cystoscopy confirms appropriate positioning of the implants. To complete the procedure, the bladder is filled and the patient voids.

The safety and efficacy of the prostatic urethral lift procedure for the treatment of benign prostatic hypertrophy have been established. It is a useful therapeutic option for men with symptomatic BPH who have failed conventional pharmacologic therapy, are unable to tolerate other surgical procedures and meet patient selection criteria.

Patient selection criteria

Candidates for the prostatic urethral lift procedure must meet all of the following guidelines:

- Age 50 years or older
- A documented diagnosis of symptomatic BPH of the lateral lobes of the prostate, including but not limited to the following symptoms:
  - Difficulty starting and stopping urination (hesitancy and straining)
  - Decreased strength of the urine stream (weak flow)
  - Dribbling after urination
  - Feeling that the bladder is not completely empty
  - An urge to urinate again soon after urinating (urgency)
  - Pain during urination (dysuria)
  - Nocturia — waking up several times during the night with the urge to urinate
  - Frequent urinary tract infections secondary to urinary obstruction
- Documented failure of, inability to tolerate, or undesirable side effects of pharmacologic interventions for BPH, including, but not limited to:
  - Alpha blockers such as Uroxatral, Cardura, Rapaflo, Flomax or Hytrin
  - 5-alpha reductase inhibitors for BPH, such as Avodart or Proscar
  - Combination drugs using both an alpha blocker and a 5-alpha reductase inhibitor
- Documentation by the attending surgeon and another physician (such as the patient’s primary care physician) of the patient’s inability to tolerate a surgical procedure requiring anesthesia due to physical factors or comorbid conditions including, but not limited to coagulopathies, respiratory conditions or cardiovascular disease.