Title

Ultrasounds:

- Breast
- Cranial
- Duplex scans
- Fetal
- Obstetrical
- Intravascular
- Prostate
- Transvaginal
- Transrectal
- Bone Density
- Abdominal Aortic Aneurysm
- Evaluation of Paranasal Sinuses
- Carotid Artery Intimal-medial Thickness (IMT)

Related Policy:

MRI-guided High Intensity Ultrasound Ablation of Uterine Fibroids, #331
Bone Densitometry, #034

When services may be medically necessary (covered) for all products including Medicare HMO Blue and Medicare PPO Blue

Transrectal Ultrasound

Transrectal ultrasound may be considered medically necessary (covered) for the following **prostatic** conditions:[1]

- local staging of prostate cancer in patients with established diagnosis of prostate cancer[1]
- monitoring of response to therapy in patients with prostate cancer[1]
- measuring size/ volume of prostate tissue prior to radiation therapy[1]
- evaluation of prostate for finding foci of possible cancerous tissue in asymptomatic patient with normal digital rectal examination (DRE) but elevated PSA levels[1]
- abnormal gland upon exam such as palpable nodules or asymmetry,[1] or in BPH patients as preoperative assessment for covered therapeutic procedures[10]
- examination of seminal vesicles in patients being evaluated for infertility[1]
- evaluation of suspected prostatitis or prostatic abscess[1]
- congenital and acquired cystic conditions of prostate, seminal vesicles, and related tissue.[1]

Transrectal ultrasound may be considered medically necessary (covered) for the following **anorectal** conditions:[1]

- clinical staging of a patient with rectal carcinoma[1]
- evaluation of patients who have had definitive treatment for carcinoma of the rectum where recurrent disease is noted[1]
- evaluation of patients with an anal or rectal fistula[1]

- diagnostic evaluation of malignant or benign perirectal tumors such as, but not limited to villous adenomas, chordomas, leiomyosarcomas, and dermoid cysts[1]
- evaluation of anal and/or rectal or perirectal abscesses.[1]

Transrectal ultrasound may be considered medically necessary (covered) for ultrasonographic guidance of prostatic needle biopsy, for obtaining prostatic tissue for pathologic examination.[1]

When services are investigational (not covered) for all products including Medicare HMO Blue and Medicare PPO Blue

Transrectal Ultrasound

T**ransrectal ultrasound** is considered investigational (not covered) for conditions not listed above.[1]

When services may be medically necessary (covered) for all products including Medicare HMO Blue and Medicare PPO Blue

Ultrasound during pregnancy

Obstetrical ultrasounds may be considered medically necessary (covered) for the following procedure codes when submitted for one of the indications below:

76801-76802: first trimester fetal and maternal examination (<14 weeks 0 days)
76805[22] and 76810: after first trimester fetal and maternal examination (> or = 14 weeks 0 days gestation)
76811 or 76812: fetal/maternal evaluation including fetal anatomic evaluation
76815: limited obstetrical ultrasound.[7]
76816: follow-up obstetrical ultrasound
76817: obstetrical ultrasound, transvaginal
76818: fetal biophysical profile, with non-stress
76819: fetal biophysical profile, without non-stress

Indications:

- Threatened or missed abortion[7] (ICD-9-CM 632, 640.03)
- Vaginal bleeding/Antepartum hemorrhage[7] (ICD-9-CM 641.30-641.33, 641.80-641.93)
- Spotting complicating pregnancy (ICD-9-CM 649.53)
- Multiple gestation[7] (ICD-9-CM 651.00-651.93)
- Abnormal presentation7 (ICD-9-CM 652.00-652.93)
- Fetal death[7] (ICD-9-CM 656.43)
- Pre-term delivery indicator.[4,7] (ICD-9-CM 644.03, 644.13)
- Congenital malformation (fetal or maternal)[7] (ICD-9-CM 654.03, 654.33, 654.43, 654.53, 654.63, 654.73, 654.93, 655.03, 655.13, 655.23, 655.33, 655.43, 655.53, 655.63, 655.83, 655.93, 740.0-759.9)
- Polyhydramnios/oligohydramnios[7] (ICD-9-CM 657.03, 658.03)
- Placenta previa[7] (ICD-9-CM 641.00[21], 641.03, 641.13)
- Abrupted placenta[7] (ICD-9-CM 641.23)
- Etopic pregnancy or hydatidiform mole[7] (ICD-9-CM 630, 633.00-633.91)
- Significant discrepancy between uterine size and dates[7] (ICD-9-CM 646.83**,** 649.63, 656.53, 656.63)
- Elevated maternal alpha-fetoprotein[7] (ICD-9-CM 796.5)
- Suspected uterine abnormality[7] (ICD-9-CM 654.03, 654.13, 654.23, 654.33, 654.93)
- Maternal risk factors (such as family history of congenital abnormality)[7] ICD-9-CM V19.5)
- Chronic systemic disease including but not limited to hypertension, diabetes, sickle cell disease, post-maturity (>41wks), preeclampsia or substance abuse[7] (ICD-9-CM 642.03-642.93, 645.13, 645.23, 648.00[21], 648.03 - 648.93, 766.21-766.22)
- Obesity complicating pregnancy, childbirth, or the puerperium, antepartum condition or complication (ICD-9-CM 649.13)
- Bariatric surgery status complicating pregnancy, childbirth, or the puerperium, antepartum condition or complication (ICD-9-CM 649.23)

- Fetal growth abnormality (growth retardation or macrosomia)[7] (ICD-9-CM 656.53, 656.63) (ICD-9-CM 764.90-764.99)
- Small for gestational dates (ICD-9-CM 656.50-656.53)
- Advanced maternal age (age 35 or more)[7] (ICD-9-CM 659.53, 659.63)
- Antepartum to assess cervical length as indicator of preterm delivery[4,7] (ICD-9-CM 644.03, 644.13)
- Post term pregnancy (645.13)
- Prolonged pregnancy (645.23)
- Threatened abortion (ICD-9-CM 640.03)[21]
- Antepartum Hemorrhage (ICD-(-CM 640.93, 641.30, 641.33, 641.90, 641.93) [21]
- Renal disease, pregnancy (ICD-9-CM 646.23)[21]
- Decreased fetal movement (ICD-9-CM 655.73)[21]
- Abnormal fetal heart rate (ICD-9-CM 659.73)[21]
- Premature rupture of membranes (ICD-9-CM 658.13)[21]
- Maternal injury affecting fetus or newborn (ICD-9-CM 760.5)[21]
- Vasa Previa (ICD-9-CM 663.53)[21]
- Velamentous umbilical cord insertion (ICD-9-CM 663.83, 762.6)
- Other placental conditions, abnormal placenta, and placental infarct (ICD-9-CM 656.70, 656.71, 656.73)
- Rh incompatibility (ICD-9-CM 656.13)
- Isoimmunization (Rh)- resulting fetal disease (ICD-9-CM 773.0-773.5)
- Liver disorders in pregnancy (ICD-9-CM 646.70, 646.73)
- Spontaneous abortion, without mention of complication, complete (ICD-9-CM 634.92)

One ultrasound examination per pregnancy, for the codes listed below, may be considered medically necessary (covered) for early pregnancy monitoring of the patient diagnosed with a history of infertility.[22]

- 76801-76802: first trimester (< 14 weeks 0 days)
  76817: ultrasound pregnant uterus, real time with image documentation, transvaginal **(effective June 1, 2004)** or
  76815: limited obstetrical ultrasound
- ICD-9-CM diagnosis code V23.0 (pregnancy with history of infertility) has been selected to identify history of infertility.

Note: When an obstetrical ultrasound, which examines the fetus and mother, and a follow-up obstetrical ultrasound (76816) are billed on the same day, the follow-up ultrasound will be denied. Documentation supporting medical necessity will be reviewed on appeal.

When services are considered not medically necessary (not covered) for all products including Medicare HMO Blue and Medicare PPO Blue

Ultrasound screening during pregnancy

Following the Medical Policy Administration review process, Blue Cross Blue Shield of Massachusetts has determined that **obstetrical ultrasounds** when performed as a **screening** for routine pregnancy is considered not medically necessary, as defined in the Blue Cross Blue Shield of Massachusetts subscriber certificate filed with the state Division of Insurance **except** for the following clinical indications:

- 76801-76802: first trimester fetal and maternal examination (<14 weeks 0 days)
- 76817: ultrasound pregnant uterus, real time with image documentation, transvaginal **(effective June 1, 2004)** or
  76815: limited obstetrical ultrasound **once in nine months**, for "determination of gestation for uncertain dates,"only.[7] ICD-9-CM diagnoses (V22.0 or V22.1) have been selected to identify this indication.
- 76805-76810: after first trimester fetal and maternal examination (> or = 14 weeks 0 days gestation) or
  76811-76812: fetal/maternal evaluation including detailed fetal anatomic examination, **once in nine**

months, for evaluation of possible fetal malformations (i.e. 16-20 weeks gestation). ICD-9-CM diagnoses (V28.3, V22.0, V22.1, V28.81) have been selected to identify this indication.[22]

More than one **complete obstetrical ultrasound** in a routine pregnancy is considered not medically necessary (not covered – see above).[12]

When services may be medically necessary (covered) for all products including Medicare HMO Blue and Medicare PPO Blue

First trimester assessment for Down syndrome: Combined test (also known as serial sequential testing) fetal ultrasound assessment of nuchal translucency with maternal serum assessment

One first-trimester (10-13 weeks gestation) combined screening for Down syndrome (serial sequential testing) incorporating maternal serum markers and fetal nuchal translucency may be considered medically necessary (covered) for women who are adequately counseled and desire information on the risk of having a child with Down syndrome.

Notes:

- ICD-9-CM diagnoses codes V28.3 (screening for malformation using ultrasonics) and V28.89 (Other specific antenatal screening- nuchal translucency testing) may identify the clinical reason for this assessment.
- Coding for clinical laboratory providers is listed under Coding Information section, which pertains to this **combined first trimester testing for Down syndrome.**

When services are investigational (not covered) for all products including Medicare HMO Blue and Medicare PPO Blue

First-trimester screening for detection of Down syndrome using measurement of nuchal translucency alone is considered investigational (not covered). [11]

First-trimester screening for detection of Down syndrome incorporating fetal nasal bone assessment translucency is considered investigational (not covered). [11]

3-D Obstetrical (OB)/fetal ultrasound is considered investigational (not covered).

When services may be medically necessary (covered) for all products including Medicare HMO Blue and Medicare PPO Blue

Breast Ultrasound:[15, 17] (CPT code76645)

Breast ultrasound may be considered medically necessary (covered) for the following indications:

- Evaluate non-palpable masses seen on mammography, to differentiate cysts from solid lesions[15,17]
- Evaluate the cystic or solid nature of palpable masses to determine if needle aspiration is necessary[15,17]
- Guide for aspiration, needle biopsy or wire localization procedures[2]
- Evaluate possible rupture of silicone breast prostheses in women who have signs or symptoms of rupture[15,17]
- Detect areas of inflammation to differentiate mastitis from abscess[15,17]
- Evaluate a mass, detected on physical exam or mammography, to determine if the mass is amenable to core biopsy[15, 17]
- Evaluate calcifications, to determine if an invasive component exists that would be amenable to core biopsy. [15, 17]

When services are not medically necessary (not covered) for all products including Medicare HMO Blue and Medicare PPO Blue

Breast Ultrasound

Following the Medical Policy Administration review process, Blue Cross Blue Shield of Massachusetts has determined that **breast ultrasound** to evaluate possible rupture of silicone breast prostheses for women without signs or symptoms of rupture is considered not medically necessary, as defined in the Blue Cross Blue Shield of Massachusetts subscriber certificate filed with the state Division of Insurance.[15]

When services may be medically necessary (covered) for commercial products (excluding Medicare HMO Blue and Medicare PPO Blue)

Non-invasive vascular studies

Transcranial doppler ultrasound (CPT codes: 93886, 93888, 93890, 93892, and 93893) may be considered medically necessary (covered) for diagnosis in patients with the following conditions:

- Subarachnoid hemorrhage, to check for vasospasm (vasoconstriction) of blood vessels. [3] (ICD-9-CM 430, 852.00-852.06, 852.09, 852.10-852.16, 852.19)
- Intraoperatively for patients undergoing carotid endarterectomy, to assess patterns of blood flow and to detect emboli, or severe ischemia to determine need for shunt placement. [3] (ICD-9-CM 433.10, 433.11)
- Steno-occlusive disease of the intracranial arteries[13] (437.0)
- Transient ischemic attacks or cardiovascular accidents in patients with sickle cell disease.[13,14] (282.60-282.69)
- Patients with suspected and symptomatic severe stenosis in the major basal intracranial arteries, generally with an expected narrowing of 65% or more.[5] (ICD-9-CM 433.00, 433.01, 780.2, 780.4, 785.9)
- Patients who have atherosclerosis of the vessels outside the brain (extracranial), when it is necessary to check for effects on the blood vessels inside the brain.[5] (ICD-9-CM 433.00-433.01, 433.20-433.21, 434.00-434.01, 434.10-434.11, 434.90-434.91)
- Patients with a **suspected** (not known) arteriovenous malformation (AVM), if assessment of the arterial supply and flow pattern is necessary.[5] (ICD-9-CM 747.81)

When services may be medically necessary (covered) for Medicare HMO Blue and Medicare PPO Blue only.

Transcranial doppler ultrasound (CPT codes: 93886, 93888, 93890, 93892, and 93893) may be considered medically necessary (covered) for diagnosis in Medicare HMO Blue and Medicare PPO patients with the following conditions:

- The patient has signs or symptoms of arterial or venous insufficiency or blockage.
- The patient has signs or symptoms of possible dialysis access site failure that may impact his/her clinical course.
- Evaluation is required after lower extremity bypass surgery or other revascularization procedures.
- The ordering physician has a reasonable expectation that the study outcomes will impact clinical decision making in the medical management of the patient.
- The patient is about to undergo coronary or peripheral bypass surgery and a suitable venous or arterial conduit (e.g. saphenous or radial artery) is not apparent on visual inspection.

When services may be medically necessary (covered) for all products including Medicare HMO Blue and Medicare PPO Blue

Intravascular ultrasound

Intravascular ultrasound may be considered medically necessary (covered) when used in transcatheter revascularization therapy for coronary artery disease as a technique of guiding transcatheter revascularization.[6]

When services may be medically necessary (covered) for all products including Medicare HMO Blue and Medicare PPO Blue

Duplex scans

Duplex scans of various vessels throughout the body may be considered medically necessary (covered) for the following indications.[5]

Extracranial (artery):[5] (CPT codes 93880-93882)

- carotid body cancer (ICD-9-CM 194.5)
- carotid body paraganglia (ICD-9-CM 237.3)
- retinal vascular occlusion, eye embolus (ICD-9-CD 362.30-362.37)
- hollenhorst plaque (ICD-9-CM 362.33)
- amaurosis fugax (transient arterial occlusion) (ICD-9-CM 362.34)
- carotid occlusion and stenosis (ICD-9-CM 433.10-433.11, 433.30-433.31, 780.4)
- carotid artery, dissection (ICD-9-CM 443.21)
- vertebral artery, dissection (ICD-9-CM 443.24)
- artery of neck, aneurysm of carotid artery (common) (external) (internal, extracranial portion) (ICD-9-CM 442.81)
- occlusion/stenosis vertebral artery (ICD-9-CM 433.20-433.21)
- vertebral artery syndrome (ICD-9-CM 435.1)
- subclavian artery steal syndrome (ICD-9-CM 435.2)
- vertebrobasilar artery syndrome (ICD-9-CM 435.3)
- unspecified transient cerebral ischemia (ICD-9-CM 435.9)
- acute, ill-defined cerebrovascular disease (ICD-9-CM 436)
- disturbance of skin sensation (i.e. numbness, paresthesia) (ICD-9-CM 782.0)
- speech disturbance (dysarthria, dysphasia, slurred speech) (ICD-9-CM 784.51, and 784.59)
- symptoms involving cardiovascular system (bruit, weak pulse) (ICD-9-CM 785.9)

Upper extremities (artery):[5] (CPT codes 93930-93931)

- atherosclerosis of the extremities (intermittent claudication, rest pain, ulceration, and/or gangrene) (ICD-9-CM 440.20-440.29, 440.30-440.32)
- upper extremity aneurysm (ICD-9-CM 442.0)
- subclavian artery aneurysm (ICD-9-CM 442.82)
- Raynaud's syndrome (ICD-9-CM 443.0)
- peripheral angiopathy in diseases classified elsewhere (ICD-9-CM 443.81)
- acrocyanosis (ICD-9-CM 443.89)
- acroparesthesia (simple, vasomotor) (ICD-9-CM 443.89)
- erythrocyanosis (ICD-9-CM 443.89)
- erythromelalgia (ICD-9-CM 443.82)
- unspecified peripheral vascular disease (intermittent claudication, peripheral: angiopathy and vascular disease) (ICD-9-CM 443.9)
- arterial spasm (ICD-9-CM 443.9)
- arterial embolism and thrombosis (ICD-9-CM 444.21)
- atheroembolism (upper extremity) (445.01)
- acquired arterio-venous fistula (ICD-9-CM 447.0)
- arterial stricture (ICD-9-CM 447.1)
- arterial rupture (erosion, ulcer, fistula, except arteriovenous) (ICD-9-CM 447.2)
- chronic ulcer of other specified sites (ICD-9-CM 707.8)
- gangrene (ICD-9-CM 785.4)
- injury to axillary, brachial, radial, ulnar, and other specified blood vessels (ICD-9-CM 903.01, 903.1, 903.2, 903.3, 903.4, 903.5, 903.8)

Lower extremities (artery): [5] (CPT codes 93925-93926)

- atherosclerosis of the extremities (intermittent claudication, rest pain, ulceration, and/or gangrene) (ICD-9-CM 440.20-440.29, 440.30-440.32)
- dissecting aneurysm (ICD-9-CM 441.00-441.03)
- ruptured abdominal aneurysm (ICD-9-CM 441.3)

- abdominal aneurysm without rupture (ICD-9-CM 441.4)
- iliac aneurysm (ICD-9-CM 442.2)
- aneurysm of lower extremity (aneurysm, femoral, and popliteal) (ICD-9-CM 442.3)
- Raynaud's syndrome (ICD-9-CM 443.0)
- thromboangiitis obliterans (Buerger's disease) (ICD-9-CM 443.1)
- peripheral angiopathy in diseases classified elsewhere (ICD-9-CM 443.81)
- erythromelalgia (ICD-9-CM 443.82)
- acrocyanosis (ICD-9-CM 443.89)
- acroparesthesia (simple, vasomotor) (ICD-9-CM 443.89)
- erythrocyanosis (ICD-9-CM 443.89)
- erythromelalgia (ICD-9-CM 443.89)
- unspecified peripheral vascular disease (intermittent claudication, angiopathy, vascular disease) (ICD-9-CM 443.9)
- arterial spasm (ICD-9-CM 443.9)
- arterial embolism and thrombosis (ICD-9-CM 444.22)
- atheroembolism (lower extremity) ICD-9-CM 445.02)
- acquired arterio-venous (ICD-9-CM 447.0)
- arterial stricture (arterial occlusive disease) (ICD-9-CM 447.1)
- arterial rupture (erosion, fistula, except arteriovenous of artery, ulcer) (ICD-9-CM 447.2)
- lower limbs ulcer except decubitus (unspecified, thigh, calf, ankle, heel and mid foot, other part of lower limb) (ICD-9-CM 707.10-707.19)
- ischemic leg muscles (ICD-9-CM 728.89)
- gangrene (ICD-9-CM 785.4)
- injury to common femoral artery, above profunda origin (ICD-9-CM 904.0)
- superficial femoral injury (ICD-9-CM 904.1)
- injury to popliteal, anterior and posterior tibial, and other specified blood vessels (ICD-9-CM 904.41, 904.51, 904.53, 904.7)

Extremities (veins): [5] (CPT codes 93970-93971)

- pulmonary embolism and infarction (ICD-9-CM 415.11, 415.19)
- phlebitis and thrombophlebitis of superficial vessels (femoropopliteal, and saphenous veins) (ICD-9-CM 451.0)
- phlebitis and thrombophlebitis of deep vessel (ICD-9-CM 451.11, 451.19)
- phlebitis and thrombophlebitis of femoral vein (deep) (ICD-9-CM 451.11)
- phlebitis and thrombophlebitis (popliteal, tibial, and femoropopliteal) (ICD-9-CM 451.19)
- phlebitis and thrombophlebitis, unspecified (ICD-9-CM 451.2)
- phlebitis and thrombophlebitis, superficial veins of upper extremity (ICD-9-CM 451.82)
- phlebitis and thrombophlebitis, deep veins, upper extremities (ICD-9-CM 451.83)
- phlebitis and thrombophlebitis, upper extremities, unspecified (i.e. arm) (ICD-9-CM 451.84)
- phlebitis and thrombophlebitis, axillary vein, (ICD-9-CM 451.89)
- thrombophlebitis migrans (ICD-9-CM 453.1)
- venous embolism and thrombosis of deep vessels of lower extremity (ICD-9-CM 453.40-453.42)
- venous embolism and thrombosis of deep vessels of lower extremity, unspecified (ICD-9-CM 453.9)
- acute venous embolism and thrombosis of axillary veins (ICD-9-CM 453.84)
- varicose veins with ulcer (ICD-9-CM 454.0)
- varicose veins with inflammation (ICD-9-CM 454.1)
- varicose veins with ulcer and inflammation (ICD-9-CM 454.2)
- varicose veins with other complications-edema, pain, swelling (ICD-9-CM 454.8)
- unspecified venous insufficiency (ICD-9-CM 459.81)
- collateral circulation (phlebosclerosis, venofibrosis) (ICD-9-CM 459.89)

- limb pain and swelling (ICD-9-CM 729.5, 729.81)
- Venous embolism and thrombosis of superficial vessels of lower extremity (ICD-9-CM 453.6)
- Acute venous embolism and thrombosis of superficial veins of upper extremity (ICD-9-CM 453.81)
- Acute venous embolism and thrombosis of deep veins of upper extremity (ICD-9-CM 453.82)
- Acute venous embolism and thrombosis of upper extremity, unspecified (ICD-9-CM 453.83)
- Acute venous embolism and thrombosis of subclavian veins (ICD-9-CM 453.85)
- Acute venous embolism and thrombosis of internal jugular veins (ICD-9-CM 453.86)

Visceral: [5] (CPT codes: 93975, 93976, 93978, and 93979)

Penile vessels: [5] (CPT codes: 93980-93981)

Hemodialysis access: [5] (CPT code: 93990)

When services are investigational (not covered) for all products including Medicare HMO Blue and Medicare PPO Blue

Transcranial doppler ultrasound is considered investigational (not covered) for the following:[3]

- To check for lack of blood flow to the brain, to determine if a patient is brain dead.
- Patients with migraine or tension headaches, brain infections, dementia, hydrocephalus, glaucoma, trauma, or patients undergoing heart bypass surgery, to check for patterns of brain blood flow.
- To monitor vasodilator therapy as a treatment of behavior or developmental disorders including, but not limited to, attention deficit hyperactivity disorder (ADHD), autism, or Tourette's syndrome.

When services may be medically necessary (covered) for Medicare HMO Blue and Medicare PPO Blue

Bone density ultrasound

Bone density ultrasound of the heel for Medicare HMO Blue and Medicare PPO Blue members may be considered medically necessary (covered) for diagnosing osteoporosis**,** in accordance with the Centers for Medicare and Medicaid Services regulations.

When services may be medically necessary for commercial products (excluding Medicare HMO Blue and Medicare PPO Blue)

Abdominal Aortic Aneurysm Screening

'Once-in-a-lifetime' ultrasound screening for abdominal aortic aneurysms for males aged 65 to 75 in commercial products may be considered medically necessary (as mandated by the Patient Protection and Affordable Care Act, September 25, 2010).

When services may be medically necessary (covered) for Medicare HMO Blue and Medicare PPO Blue

Abdominal Aortic Aneurysm Screening

'Once-in-a-lifetime' ultrasound screening for abdominal aortic aneurysms for male Medicare HMO Blue and Medicare PPO Blue member may be considered medically necessary in accordance with the Centers for Medicare and Medicaid services (effective January 1, 2007).

When services are investigational (not covered) for all products including Medicare HMO Blue and Medicare PPO Blue

Ultrasound as a screening test in the absence of signs or symptoms of a disease or condition is considered investigational (not covered), with the exception of '*once-in-a-lifetime'* ultrasound screening for abdominal aortic aneurysms.

Ultrasound for the evaluation of paranasal sinuses is considered investigational (not covered).[18, 28]

Ultrasonographic measurement of carotid artery intimal-medial thickness (IMT)[27] as a technique of identifying and monitoring subclinical atherosclerosis is considered investigational (not covered) for use in screening, diagnosis, or management of atherosclerotic disease.
Intravascular Doppler technique for monitoring renal venous blood flow is considered investigational (not covered).

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique circumstances may be considered in light of current scientific literature.

For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed	Prior to performance of service
Blue Cross Blue Shield of Massachusetts Provider Appeals P. O. Box 986065 Boston, MA 02298	Blue Cross Blue Shield of Massachusetts Case Creation/Medical Policy One Enterprise Drive Quincy, MA 02171 Tel: 1-800-327-6716 Fax: 1-888-282-0780

Managed care guidelines

- Any specialist visit requires a referral for Medicare HMO Blue.
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorizations are not required.

Indemnity and PPO guidelines

All authorization requirements are determined by the individual's subscriber certificate, however:

- Authorizations are required for all inpatient services
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate
- Referrals to a specialist are not required.

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Gastroenterology
CPT codes:

- **43259:** upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with endoscopic ultrasound examination
- **43231:** esophagoscopy, rigid or flexible; with endoscopic ultrasound examination
- **45341:** sigmoidoscopy, flexible; with endoscopic ultrasound examination

- **45342:** sigmoidoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy

Soft Tissue of Head and Neck ultrasound

- **76536:** ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation

Note: See footnote 28 for non-covered diagnoses for CPT code 76536 for commercial products, only.

Ultrasonic guidance for needle biopsy
CPT codes:

- **76942:** ultrasonic guidance for needle biopsy, radiological supervision and interpretation

Transrectal

- **76872:** echography, transrectal

  Note: When transrectal echography (CPT code 76872) is performed at the same session as ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation (76942), the following will occur:
  - When CPT code 76872 (26) is billed with 76942 (26) by the same provider, the same date of service, code 76942 will deny as mutually exclusive to 76872, leaving no patient balance.
  - When CPT codes 76872 and 76942, TC are billed by the same provider, same date of service, both services will process for payment.
- CPT code 76873: echography, transrectal; prostate volume study for brachytherapy treatment planning (separate procedure)

Obstetrical ultrasounds
CPT codes:

- **76801**: ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (<14 weeks 0 days), transabdominal approach; single or first gestation
- **76802:** ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (<14 weeks 0 days), transabdominal approach; each additional gestation (list separately in addition to code for primary procedure performed)

Note: CPT codes 76801 and 76802 include determination of the number of gestational sacs and fetuses, gestational sac/fetal measurements appropriate for gestation, survey of visible fetal and placental anatomical structure, qualitative assessment of amniotic fluid volume/gestational sac shape and examination of the maternal uterus and adnexa.

- **76805:** ultrasound pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (>or = 14 weeks 0 days), transabdominal approach; single or first gestation
- **76810:** ultrasound pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (>or = 14 weeks 0 days), transabdominal approach; each additional gestation. (list separately in addition to code for primary procedure)

Note: CPT codes 76805 and 76810 include determination of number of fetuses and amniotic chorionic sacs, measurements appropriate for gestational age (> or = 14 weeks 0 days), survey of intracranial/spinal/abdominal anatomy, four chambered heart, umbilical cord insertion site, placental location and amniotic fluid assessment and, when visible, examination of maternal adnexa.

- **76811**: ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; single or first gestation

- **76812:** ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; each additional gestation (list separately in addition to code for primary procedure)

Note: CPT codes 76811 and 76812 include all elements of codes 76805 and 76810 plus detailed anatomic evaluation of the fetal brain/ventricles, face heart/outflow tracts and chest anatomy, abdominal organ specific anatomy, number/length/architecture of limbs and detailed evaluation of the umbilical cord and placenta and other fetal anatomy as clinically indicated.

- **76815:** ultrasound, pregnant uterus, real time with image documentation, limited (e.g. fetal heart beat, placental location, fetal position and/or qualitative amniotic fluid volume) one or more fetuses

Note: Based on the narrative of this procedure, the examination includes the evaluation of one or more fetuses.

- **76816**: ultrasound, pregnant uterus, real time image documentation, follow-up (e.g. re-evaluation of fetal size by measuring standard growth parameters and amniotic fluid, re-evaluation of organ system(s) suspected or confirmed to be abnormal on previous scan), transabdominal approach, per fetus
- **76817**: ultrasound, pregnant uterus, real time with image documentation, transvaginal
- **76818**: fetal biophysical profile; with non-stress testing
- **76819**: fetal biophysical profile; without non-stress testing

First trimester assessment for Down syndrome: Fetal ultrasound assessment of nuchal translucency combined with maternal serum assessment
CPT codes:

- **76813**: Ultrasound pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; single or first gestation
- **76814**: Ultrasound pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; each additional gestation (List separately in addition to code for primary procedure)
- **81508:** Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score
- **81509:** Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score
- **81510:** Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)
- **81512:** Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score
- **84163**: Pregnancy-associated plasma protein-A (PAPP-A)
- **84702**: Gonadotropin, chorionic (hCG); quantitative
- **84704:** Gonadotropin, free beta chain

Note: First trimester screening for detection of Down syndrome using measurement of the nuchal translucency alone is **investigational** and considered non-covered because it does not meet the Blue Cross Blue Shield of Massachusetts Medical Technology Assessment Guidelines, #350.

Breast Ultrasound
CPT code:

- **76645:** echography, breast(s) (unilateral or bilateral), B-scan and/or real time with image documentation

Note: See footnote 17 for covered diagnoses for CPT code 76645 for ***commercial products and for Medicare HMO Blue and Medicare PPO Blue.***

Bladder Ultrasound
CPT code:

- **51798:** measurement of post voiding residual urine and /or bladder capacity by ultrasound, non-imaging

Note: There is no additional reimbursement for the interpretation of this scan. The following codes should not be used to report this bladder ultrasound, as the work associated with this bladder ultrasound is significantly less than that associated with these procedures: 76770, 76775, 76856 and 76857.

Transcranial/extracranial
CPT codes:

- **93880:** duplex scan of extracranial arteries; complete bilateral study
- **93882:** duplex scan of extracranial arteries; unilateral or limited study
- **93886:** transcranial doppler study of the intracranial arteries; complete study
- **93888:** transcranial doppler study of the intracranial arteries; limited study
- **93890:** transcranial doppler study of the intracranial arteries; vasoreactivity study
- **93892:** transcranial doppler study of the intracranial arteries; emboli detection without intravenous microbubble injection
- **93893:** transcranial doppler study of the intracranial arteries; with intravenous microbubble injection

Duplex scan/extremities: Arterial
CPT codes:

- **93930:** duplex scan of *upper extremity* arteries or arterial bypass grafts; complete bilateral study
- **93931**: duplex scan of *upper extremity* arteries or arterial bypass grafts; unilateral or limited study
- **93925**: duplex scan of *lower extremity* arteries or arterial bypass grafts; complete bilateral study
- **93926:** duplex scan of *lower extremity* arteries or arterial bypass grafts; unilateral or limited study

Duplex scan/extremities: Venous
CPT codes:

- **93970:** duplex scan of extremity veins including response to compression and other maneuvers; complete bilateral study
- **93971:** duplex scan of extremity veins including response to compression and other maneuvers; unilateral or limited study

Duplex scan/penile vessels
CPT code

- **93980:** duplex scan of arterial inflow and venous outflow of penile vessels; complete study and 93981 for follow-up or limited study

Duplex scan/abdominal/pelvic/scrotal/retroperitoneal
CPT code

- **93975:** duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study; and 93976 for limited study

Duplex scan/aorta/IVC/iliac/bypass grafts
CPT codes

- **93978:** duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; complete study;
- **93979**: duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; unilateral or limited study

Duplex scan/hemodialysis access
CPT code

- **93990**: duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)

Intravascular ultrasound (non-coronary)
CPT code

- **37250:** intravascular ultrasound (non-coronary vessel) during therapeutic intervention; initial vessel and
- **37251**: intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel

Note: For the radiological supervision and interpretation, bill 75945.

Urology
CPT codes:

- **51798**: measurement of post voiding residual urine and /or bladder capacity by ultrasound, non-imaging
- **76872:** echography, transrectal

Note:

- When CPT code 76872 (26) is billed with 76942 (26) by the same provider, the same date of service, code 76942 will deny as mutually exclusive to 76872, leaving no patient balance.
- When CPT codes 76872 and 76942, TC are billed by the same provider, same date of service, both services will process for payment.

Modifiers

- **26**: professional component
- **TC**: technical component

The procedures noted below will reject as non-covered, ***for commercial products and for Medicare HMO Blue and Medicare PPO Blue,*** leaving **no** patient balance, as these procedures do not meet our Medical Technology Assessment Guidelines.

Ultrasound of paranasal sinuses

- HCPCS Level II code S9024, paranasal sinus ultrasound

Ultrasound measurement of carotid intimal-medial thickness as assessment of subclinical atherosclerosis
CPT code

- **0126T:** common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment

The procedures noted below will reject as non-covered, leaving **no** patient balance, as these procedures do not meet our Medical Technology Assessment Guidelines. However, in accordance with CMS guidelines, the following procedures are covered for ***Medicare HMO Blue and Medicare PPO Blue, only.***

Ultrasound/bone density measurement
CPT code

- **76977:** report ultrasound bone density measurement and interpretation, peripheral site(s), any method

Abdominal aortic aneurysm (AAA) screening
HCPCS code

- **G0389**: ultrasound B scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening

Policy update history

TRUS: Issued 1/88, reviewed 10/95. Transcranial US: Issued 8/92. Medicare guideline published 7/92. Policy revised 5/96 based upon the 8/94 TEC assessment below and one from 1992, as well as a literature review through 1/95 by TEC. Revised 6/97 to include special consideration coverage for prostate ultrasound for abscesses and as part of an infertility evaluation. Updated 9/97 to remove statement regarding procedure 76942 (ultrasonic guidance for needle biopsy, radiological supervision and interpretation) is denied as mutually exclusive to 76872 (transrectal ultrasound) when performed on the same day by the same provider. Updated 12/97 to include coverage consistent with new local Medicare policy for transrectal ultrasound (CPT 76872) for prostatic and anorectal conditions; prostatic needle biopsy (55700) aided by ultrasonographic guidance (76942) for obtaining prostatic tissue for pathologic exam; CPT codes added for transcranial doppler ultrasound, extracranial artery, upper and lower extremities, visceral, and hemodialysis access. Updated 1/98 to include the Massachusetts Chapter ACOG's recommendation on ultrasound as preterm delivery indicator; ICD-9-CM diagnoses codes. Updated 6/98 to include ICD-9-CM diagnoses codes for complete and limited ultrasound during pregnancy. Updated 10/98 to include 1999 CPT code, 76977. Reviewed 1/99, no changes in coverage were made. Updated 5/99 to add billing information for procedure code G0050. Updated 6/99 to include coverage for abnormal gland upon exam such as palpable nodules or asymmetry. Updated 8/99 to include ICD-9-CM 415.11 and 415.19. Updated 10/99 to include billing information for endoscopic ultrasound: CPT code 43259, upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with endoscopic ultrasound examination. Updated 1/00 to include billing information for CPT code 76873. Updated 2/2000 to exclude coverage for ultrasound of the heel for diagnosing osteoporosis and selecting patients for pharmacologic, effective 7/2000, except for Medicare HMO Blue members. Reviewed 4/01, no changes in coverage were made. Updated 6/01 to exclude coverage for ultrasound as a screening test in the absence of signs or symptoms of a disease or condition, effective 7/1/01 and to clarify coverage for TRUS in BPH patients as preoperative assessment for covered therapeutic procedures. Updated 10/01 to clarify coverage for duplex scans for carotid occlusion and stenosis and to include coverage for disturbance of skin sensation (i.e. numbness, paresthesia). Updated 12/01 to expand coverage for 1 complete obstetrical ultrasound per pregnancy for fetal malformations, routine pregnancy, and to exclude coverage for 2 limited ultrasounds with routine pregnancy, effective 3/15/02; and to clarify coverage exclusion for nuchal translucency screening. Updated 1/02 to include coverage for transcranial doppler for steno-occlusive disease of the intracranial arteries and transient ischemic attacks or cardiovascular accidents in patients with sickle cell disease; effective 2/02; and to expand coverage for breast ultrasound. Updated 8/02 to include coverage for 1 complete OB ultrasound as an indication for early pregnancy monitoring for history of infertility. Updated 10/02 to include coverage for intravascular ultrasound when used in transcatheter revascularization therapy for coronary artery disease as a technique of guiding transcatheter revascularization, effective 10/02. Updated 2/2003 to clarify coverage exclusion for ultrasound for the evaluation of paranasal sinuses. Updated 2/2003 to include new medically necessary coverage criteria language, non-invasive vascular studies, for Medicare HMO Blue, Medicare PPO Blue, and Medex based on NHIC LMRP #01-R2-09 (effective 7/15/02). Reviewed 5/03 MPG Cardiology, no changes in coverage were made. Updated 6/03 to include additional medically necessary diagnoses considered covered for OB Ultrasounds. Additional approved diagnoses are identified in policy by notation of footnote (21). OB ultrasound editing information clarified: 2002 regarding procedure code 76805, and 2003 coding update to related edit, footnote (22). Reviewed 6/03 MPG Urology, no changes in coverage were made. Reviewed 9/03 MPG hematology/oncology, no changes in coverage were made. Reviewed 10/03 MPG Obstetrics and Gynecology and Infertility, no changes in coverage were made. Reviewed 1/04 MPG Neurology, no changes were made. Updated to include coverage indication for small for gestational dates, effective 6/04. Reviewed 6/04 MPG Urology, no changes in coverage were made. Reviewed 9/04 MPG Hematology and Oncology, no changes in coverage were made. Reviewed 11/04 MPG Gastroenterology, Nutrition and Organ Transplantation, no changes in coverage were made. Updated 1/05 to include coverage for first-trimester screening of Down syndrome, which consists of a calculation of risk based on maternal age, human chorionic gonadotropin, pregnancy-associated plasma protein A, and ultrasonic measurement of fetal nuchal translucency for women who are adequately counseled and desire information on the risk of having a child with Down syndrome; effective April 2005. Reviewed 1/05 MPG Neurology, no changes in coverage were made. Updated 2/05 to include references and rationale from BCBSA national policy issued 2/04 relating to non coverage of paranasal sinus ultrasound. Updated 3/2005 to clarify coverage

information pertaining to nuchal translucency which is considered an investigational assessment for Down syndrome when performed as a stand alone procedure, updated to include additional BCBSA National policy rationale information-foot note #11, and to clarify appropriate procedure coding for the combined tests for assessment for Down syndrome. Reviewed 4/05 BCBSA national policy issued 3/05 after an updated literature review; no change in coverage exclusion of paranasal ultrasound. Reviewed 6/05 MPG-Urology, no changes in coverage were made. Reviewed 9/05 MPG Hematology and Oncology, no changes in coverage were made. Reviewed 10/05 MPG Obstetrics and Gynecology, no changes in coverage were made. Reviewed 11/05 MPG Gastroenterology, Nutrition and Organ transplantation, no changes in coverage were made. Reviewed 1/06 MPG-Neurology, no changes in coverage were made. Updated 3/06 to merge covered indications for breast ultrasound: ICD-9-CM diagnoses 611.79, 611.8, and 611.9 no longer restricted to Medicare Advantage Plans, now covered for all plans. Clarified covered diagnoses for the following Duplex scans: CPT procedure codes 93880/93881 added diagnoses codes (443.20-443.21, 435.1, 435.2, and 435.3, effective 3/06), CPT procedure codes 93925/93926- added diagnoses codes (707.11-707.19, 443.82, and 445.02, effective 3/06), CPT procedure codes 93930/93931 added diagnoses codes (443.82, 445.01, 903.4 and 903.5, effective 3/06), and CPT procedure codes 93970/93971- added diagnoses codes 451.82-451.84, 451.89, 454.1 and 459.81, effective 3/06). Reviewed 4/06 MPG Cardiology, no changes in coverage were made. 7/2006 clarified covered clinical indications for procedure codes 93925, 93926, 93930, and 93931- added ICD-9-CM diagnoses 440.30-440.32, effective 6/30/2006. Reviewed 9/06 MPG Hematology and Oncology, no changes in coverage were made. 10/06 updated list of covered *medically necessary* clinical indications to include Vasa Previa (ICD-9-CM 663.53), effective 10/2006, footnote #21edited. 10/06 Updated to exclude coverage for transcranial Doppler ultrasound for monitoring vasodilator therapy as a treatment of behavior or developmental disorders including, but not limited to, attention deficit hyperactivity disorder (ADHD), autism, or Tourette's syndrome, effective January 2007. Reviewed 10/06 MPG-Obstetrics and Gynecology; no changes in coverage were made. 11/2006 updated list of covered *medically necessary* clinical indications to include Velamentous umbilical cord insertion (ICD-9-CM 663.83, 762.6), effective 11/2006 going forward. Reviewed 11/06 MPG-Gastroenterology, Nutrition and Organ Transplants, no changes in coverage were made. Reviewed 1/07 MPG Neurology, no changes in coverage were made. Updated 2/07 to include coverage for AAA screening for Medicare HMO Blue and Medicare PPO Blue members, only, effective 1/1/07; and based on CMS' National Coverage Determination; footnote #24 added. Updated 3/07 to add ICD-9 CM diagnosis 649.63 (uterine size date discrepancy) as a covered medically necessary clinical indication when billed with ultrasound during pregnancy, effective 10/1/06. 3/07 updated and corrected ICD-9-CM diagnoses range 433.20-433.21 reporting vertebral artery occlusion/stenosis noted under extra cranial artery CPT codes 93880 and 93882. Added covered diagnoses for procedure codes 93880, and 93882, effective 4/2007. BCBSA medical policy comparison review completed- *First-trimester detection of Down syndrome using fetal ultrasound assessment of nuchal translucency combined with maternal serum assessment*; footnote #11 updated to include scientific references, and 2005-2007 literature reviews; BCBSA policy statement unchanged. Reviewed 4/07 MPG Cardiology, no changes in coverage were made. Updated 6/18/07 to reflect addition of ICD-9-CM code range 656.70-656.73 requested by IC, Rockland, effective 6/07. Reviewed 6/07 MPG Urology, no changes in coverage were made. Updated 9/23/07, to add implementation of procedure to diagnosis editing to support coverage of CPT codes 93970-93971 when used with diagnosis code 454.8. *Effective 9/07*. Reviewed 9/07 MPG Hematology and Oncology, no changes in coverage were made. Updated 10/16/07 to reflect addition of ICD-9 code 362.30 - eye embolus to the list of covered indications for CPT code 93880/93882 as requested by IC, Rockland, effective 10/07. Reviewed 10/07 MPG - Obstetrics and Gynecology, no changes in coverage were made. Reviewed 11/07 MPG-Gastroenterology, Nutrition and Organ Transplants, no changes in coverage were made. Updated 12/07 to add clinical indications: Rh incompatibility (ICD-9-CM 656.13) Isoimmunization (Rh) - resulting in fetal disease; (ICD-9-CM 773.0-773.5) to the list of medically necessary indications for OB ultrasound, effective 12/2007. Updated 1/25/08 to add clinical indications: liver disorders in pregnancy (ICD-9-CM 646.70, 646.73) to the list of medically necessary indications for OB ultrasound, effective 2/2008. Updated 1/08 to add clinical indications: spontaneous abortion, without mention of complication, complete (ICD-9-CM 634.92) to the list of medically necessary indications for OB ultrasound procedures; CPT codes 76801, 76802, 76805, 76810, and 76817, Effective 1/2008. 2/08 Completed comparison review BCBSA medical policy *Ultrasonographic Evaluation of Skin Lesion;* national policy statement unchanged- *investigational.* BCBSMA benchmarking of the BCBSA medical policy unchanged;

#007 clarified and brought in-line with #400; footnote #26 added to provide rationale and literature references. Completed comparison review BCBSA medical policy *Ultrasonographic Measurement of Carotid Intimal-Medial Thickness as an Assessment of Subclinical Atherosclerosis;* national policy statement unchanged-*investigational*. BCBSMA benchmarking of the BCBSA medical policy unchanged; #007 clarified and brought in-line with #400; footnote #27 added to provide rationale and literature references. Completed comparison review of BCBSA medical policy *First Trimester Detection of Down Syndrome;* BCBSA policy unchanged. BCBSMA benchmarks the BCBSA policy which is reflected in this document. Reviewed 1/08 MPG-Neurology, no changes in coverage were made. Reviewed 4/08 MPG-Cardiology, no changes in coverage were made. Clarified 5/08, medically necessary indications with the addition of *Spotting complicating pregnancy* as a covered clinical indication, May 2008. Updated 5/08 after review of BCBSA policy issued 4/08 without change in policy statements related to first trimester detection of Down syndrome; added rationale and 1 reference under footnote 11 as well as BCBSMA's coverage effective date of April 2005. Clarified 6/08, medically necessary indications with the addition of *obesity complicating pregnancy, childbirth, or the puerperium, antepartum condition or complication* (ICD-9-CM 649.13) and *Bariatric surgery status complicating pregnancy, childbirth, or the puerperium, antepartum condition or complication* (ICD-9-CM 649.23), effective June 2008. Reviewed 6/08 MPG-Urology, no changes in coverage were made. 8/08 comparison review of the BCBSA National medical policy *Transcranial Doppler Ultrasound*; no changes to the BCBSA coverage criteria but CPT coding added during their policy editing; BCBSMA continues to include the BCBSA criteria in this document's coverage criteria. Reviewed 10/08 MPG-Hematology and Oncology, no changes in coverage were made. Reviewed 10/08 MPG-Obstetrics and Gynecology, no changes in coverage were made. Reviewed 11/08 MPG-Gastroenterology, Nutrition and Organ Transplants, no changes in coverage were made. Updated 1/09 to clarify covered clinical indications for OB ultrasound providing 2009 diagnoses coding which represents a higher degree of specificity: evaluation of possible fetal malformations (i.e. 16-20 weeks gestation), ICD-9-CM diagnosis V28.81 (*Other specified antenatal screening-encounter for fetal anatomic survey*); and nuchal translucency testing ICD-9-CM diagnosis V28.89, (*Other specific antenatal screening- nuchal translucency testing.).* 1/09 Comparison review of BCBSA National medical policy, *Ultrasound for the Evaluation of Paranasal Sinuses;* investigational status which BCBSMA benchmarks is unchanged; related footnote (18) clarified; edit applied to CPT procedure code 76536 information noted in footnote #28. Reviewed 1/09 MPG-Neurology and Neurosurgery, no changes in coverage were made. Updated 2/09 to correct a typographical error with ICD-9-CM diagnosis for retinal vascular occlusion when billed with CPT codes 93880, 93882; correct range 362.30-362.37. Reviewed 4/09 MPG-Cardiology, no changes in coverage were made. Reviewed 6/09 MPG-Urology, no changes in coverage were made. Updated 8/09 after review of BCBSA policy, Ultrasonographic Measurement of Carotid Intimal-Medical Thickness as an Assessment of Subclinical Atherosclerosis; without change in coverage exclusion of the technique used in the screening, diagnosis or management of atherosclerotic disease; added rationale and references 21-25 under footnote 27. Reviewed 9/2009 MPG-Hematology and Oncology, no changes in coverage were made. Updated 11/09 to remove deleted 2008 HCPCS Level II code S3618. Updated 4/10 to clarify the covered clinical indications for CPT procedure code 76815 to include ICD-9-CM diagnosis code 634.92, complete spontaneous abortion without mention of complication; editing to the Code information, Policy history update and Scientific background sections to align with new policy format. Updated 5/1/2010 to remove the policy statement regarding wireless capsule endoscopy from policy # 007, Ultrasound; see new policy document #185, Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon. Reviewed 4/2010 MPG-Cardiology, no changes in coverage were made. Updated 6/10; new 2010 ICD-9-CM diagnosis codes 784.51, and 784.59 added replacing diagnosis code 784.5 for Duplex scan, extracranial arteries. Reviewed 6/2010 MPG-Urology, no changes in coverage were made. Updated 7/10 based on a comparison review of the BCBSA national policy, First-Trimester Detection of Down Syndrome Using Fetal Ultrasound Markers Combined with Maternal Serum Assessment; the national policy, which BCBSMA benchmarks, clarified that fetal nasal bone assessment is considered investigational and changed their policy title. See footnote 11 for updated rationale and added references 7-11 and 14-27. Reviewed 9/2010 MPG-Hematology and Oncology, no changes in coverage were made. Updated 10/2010 to include coverage for a ***'once-in-a-lifetime'* ultrasound screening for abdominal aortic aneurysms** for males aged 65 to 75 in commercial products as of September 25, 2010 as mandated by Patient Protection and Affordable Care Act. Reviewed 10/2010 MPG Obstetrics and Gynecology, no changes in coverage were made. Updated 11/2010,

adding references to footnote 27. Reviewed 11/2010 MPG Gastroenterology, Nutrition and Organ Transplantation, no changes in coverage were made. Updated 1/12/2011 to remove information regarding ultrasonographic evaluation of skin lesions. Ultrasonographic Evaluation of Skin Lesions is addressed in policy #303. Also, updated to clarify "combined test" under screening for Down's Syndrome is also known as "serial sequential testing." Updated 1/2011 MPG – Neurology and Neurosurgery, no changes in coverage were made. Reviewed 4/2011 MPG – Cardiology and Pulmonology, no changes in coverage were made. Reviewed 7/2011 MPG – Hematology and Oncology, no changes in coverage were made. Reviewed 9/2011 MPG – Urology, Obstetrics and Gynecology, no changes in coverage were made. Updated 10/12/2011 to include reference to covered diagnosis code 453.84 **(**acute venous embolism and thrombosis of axillary veins) for CPT codes 93970 and 93971, effective October 2011. Reviewed 10/2011 MPG GI, Nutrition and Organ Transplantation, no changes in coverage were made. Updated 12/2011 with additional references based on BCBSA policy, 4.01.14 First-Trimester Detection of Down Syndrome Using Fetal Ultrasound Markers Combined with Maternal Serum Assessment, 3/2011. Updated 12/2011 with additional references based on BCBSA policy. Reviewed 1/2012 MPG – Neurology and Neurosurgery, no changes in coverage were made. Updated 2/2012 to clarify ongoing non-coverage of 3-D Obstetrical (OB)/fetal ultrasound and intravascular Doppler technique for monitoring renal venous blood flow. These same procedures are addressed in document 400. Updated 2/13/2012 to clarify the list of additional covered diagnoses for CPT codes 93970-93971: 453.6; 453.81; 453.82; 453.83; 453.85; 453.86. Updated 3/2012 with additional references based on BCBSA national policy, reviewed 7/ 2011. Reviewed 4/2012 MPG-Cardiology and Pulmonology, no changes in coverage were made. Updated 6/2013 to include 5-digit diagnoses codes: 611.81, 611.82, 611.83 and 611.89. Updated 8/19/2014 to include 793.82 inconclusive mammogram as a covered diagnosis for 76645 - Ultrasound, breast(s) (unilateral or bilateral), real time with image documentation. Effective 8/19/2014.

Scientific background, Rationale and References

[1] **Transrectal Ultrasound**: Based on the October/November 1997 Medicare Newsletter, pages 67-69. See also local Medicare policy at the following web address: **http://www.medicarenhic.com/,** and CMS guidelines CIM 50-7 at: **http://www.cms.hhs.gov/manuals/06_cim/ci50.asp#_1_8**
Breast ultrasound issued 7/92. This policy is in compliance with local Medicare guidelines.

[2] Based upon an 11/95 TEC (Technology Evaluation Center) assessment evaluating the use of fine-needle aspiration (FNA), needle core bx (NCB), and open surgical bx (SB) for non-palpable breast lesions evaluated medical literature from 1991-10/95. BI-RADS staging classifications were used for mammographic determinations of "probably benign, suspicious, and highly suspicious." The patient population comprised women undergoing screening mammography, with non-palpable lesions.

FNA was evaluated in 17 studies of almost 3000 lesions. The overall insufficiency rate (inability to make definitive interpretation) of 12% (coordinate-grid loc) or 33% (stereotactic loc). FNA is not as beneficial or as reliable as core bx or open surgical biopsy for non-palpable breast lesions. Diagnoses of ductal CIS and degree of invasion are not possible with so few cells.

NCB was evaluated in 6 studies of over 5000 lesions. The overall insufficiency rate was 0.4%, with the largest study (Parker 1994) reporting 0.25%. Five NCBs were required to result in such rates. There is no direct comparison between NCB and SB, but it appears to have results similar to surgical specimens.

SB, although the gold standard, did not correlate with mammography in about 4% of lesions. Due to the risks of surgery and anesthesia, SB is reserved for non-palpable lesions considered suspicious or highly suspicious for malignancy. The larger tissue specimen provides more detailed information for treatment planning.

[3]Based on the Blue Cross Blue Shield Association national medical policy, **Transcranial Doppler ultrasound,** # 6.01.07.

Policy rationale
This policy is based in part a 1994 TEC Assessment (1) that evaluated the following indications for transcranial Doppler:

- monitoring for vasospasm in patients with subarachnoid hemorrhage
- intraoperative assessment and monitoring of collateral blood flow and embolizations in patients undergoing carotid endarterectomy
- evaluation of patients with transient ischemic attacks or cerebrovascular accidents for intracranial artery stenosis
- evaluation of patients who have sickle cell disease without symptoms of transient ischemic attack (TIA) or cerebrovascular accident (CVA) for intracranial artery stenosis

The TEC Assessment concluded that for the first two indications listed above, transcranial Doppler met the TEC criteria, while indications 3 and 4 did not. It should be noted that the 1994 TEC Assessment also considered the recommendations of a 1990 policy statement issued by the American Academy of Neurology. (2)

The current policy updates the fourth indication, i.e., transcranial Doppler in patients with sickle cell disease, based on additional randomized controlled studies. Specifically, in 1998, Adams and colleagues reported on a trial of chronic blood transfusions in 130 children with sickle cell anemia and abnormal results on TCD. (3) An abnormal TCD was defined as 200 cm per second in either the internal carotid artery or the middle cerebral artery. A total of 63 patients were randomized to receive transfusions to achieve a target hemoglobin S concentration of less than 30% of total hemoglobin; children received transfusions every 3 to 4 weeks. The remaining 67 patients received standard care. There was a significant decrease in the incidence of stroke in the transfusion group, leading to premature termination of the trial. This trial did not address how long transfusion should be continued as a means of preventing stroke or at what intervals repeated TCD is warranted. Despite the positive results of the trial, chronic transfusion therapy presents its own set of risks that may limit enthusiasm for this approach. For example, treatment of iron overload will likely be required. In addition, the overall safety of the blood supply is a concern. (4)

2006 Update
This policy update is focused on the role of TCD as a technique to monitor vasodilator therapy in patients with developmental or behavioral disorders. It has been hypothesized that these disorders are related to cerebral vasospasm that can be relieved by vasodilator therapy. However, a search of the MEDLINE database failed to identify any peer-reviewed articles focused on this therapy.

References:

1. 1994 TEC Assessment, tab 20.
2. American Academy of Neurology Therapeutics and Technology Assessment Subcommittee. Assessment: transcranial Doppler. Neurology 1990; 40(4):680-1.
3. AdamsRJ, McKie VC, Hsu L et al. Prevention of a first stroke by transfusions in children with sickle cell anemia and abnormal results on transcranial Doppler ultrasonography. N Engl J Med 1998; 339(1):5-11.
4. Cohen AR. Sickle cell disease—new treatments, new questions. N Engl J Med 1998; 339(1):42-4.

Ultrasound in pregnancy issued 5/89.
Updated 4/97 to include ICD.9.CM diagnoses and correct footnote error. No changes were made to coverage.

[4] Based upon the 3/96 National Blue Cross Blue Shield Association Policy on Ultrasound in Maternity Care.

[5] Based on local Medicare guidelines. For more information see Medicare's policy CIM 50-6 at the following web address**:** http://www.cms.hhs.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS021321

[6] Based upon the 3/15/99 National Blue Cross Blue Shield Association Policy on Intravascular Ultrasound (IVUS) Imaging.

[7] Added 1/98 based on recommendations made by the Massachusetts Chapter of the American College of Obstetrics and Gynecology.

[8] Based on the 12/99 TEC (Technology Evaluation Center) assessment of medical literature from 1986-12/99 on heel US for diagnosing osteoporosis and selecting patients for pharmacologic treatment. The assessment analyzed whether ultrasound of the heel improves health outcomes by identifying patients at high risk for fractures and who would benefit from drug therapy.

FDA Status: Bone ultrasonometers with premarket FDA approval:

- **Hologic's Sahara Clinical Bone Sonometer**® for quantitative US measurement of the calcaneus. Results may be used in conjunction with other clinical risk factors, as an aid in diagnosing osteoporosis and conditions leading to decreased bone density, and in the determination of fracture risk.
- **Myriad Soundscan**® for quantitative US measurement of tibia. Results may be used in conjunction with other clinical risk factors in diagnosing osteoporosis and medical conditions leading to decreased bone strength and to determine fracture risk.
- **Lunar Achilles+®/Lunar Achilles Express**® for measuring US variables of the os calcis to provide "Stiffness Index".

Health outcomes: Literature evidence comprised 4 prospective studies, and a few cross sectional studies. Two prospective studies (2 year follow-up) compared predictive ability of US with DEXA. Both reported that US was essentially equivalent to DEXA in predicting fracture risk; hip DEXA was more predictive for hip fractures than was heel US. The smaller studies concurred with results of the larger studies. In general, for every one SD decrease in US parameters, there is a 1.5-2.5 times increased risk for future fracture. However, several large studies (pooled n=over 8000) demonstrated only a modest correlation between heel broadband ultrasound attenuation and DEXA of the hip (r=0.47, CI=0.30-0.87).

There appears to be no evidence that patients identified as high risk by US benefit from treatment. US' sensitivity and specificity in identifying patients that may benefit from treatment was based on an empirical evidence of the correlation between broadband US and DEXA. It was estimated that 43-76% of patients who would benefit from treatment were in fact correctly identified by US. Furthermore, 75-90% who would **not** benefit from treatment were also correctly identified by US. Given these broad ranges, it is difficult to make conclusions about whether health outcomes would be improved as a result of using US.

Comparisons: There are multiple methods to evaluate bone mineral density, however none can be truly acknowledged as the gold standard. Hip DEXA is most commonly used, and is most widely studied. The use of hip DEXA to identify patients who will benefit from drug therapy has been established by randomized controlled trials. While US of the heel may be more convenient, and does not involve radiation, it is not been proven to be as beneficial as DEXA in identifying patients for osteoporosis drug therapy.

[9]Medicare policy is developed separately from BCBSMA policy. While BCBSMA policy is based upon scientific evidence, Medicare policy incorporates scientific evidence with local expert opinion, and governmental regulations from CMS (Centers for Medicare and Medicaid Services) and the US Congress. While BCBSMA and Medicare policies may differ, our Medicare HMO Blue and Medicare PPO Blue members must be offered the same services as Medicare offers. In many instances, BCBSMA policies offer more benefits than does Medicare policy.

[10]Recommendations from the Medical Policy Group and Massachusetts Association of Practicing Urologists, 6/01.

[11] Based on BCBSA national policy 4.01.14, First-Trimester Detection of Down Syndrome Using Fetal Ultrasound Markers Combined with Maternal Serum Assessment, issued 3/2010.

Rationale
In studies of first-trimester screening, the laboratory and imaging components of the screening are performed in a coordinated fashion. This process results in a set of predictions of Down syndrome, which can be summarized by receiver operator characteristic (ROC) curve analysis or sensitivity and specificity estimates. Although multiple cutoff points are possible, a standard method of presenting results is to report the sensitivity at the cutoff that produces a 5% false-positive rate. In actual practice, however, patients are not just informed of a "positive" or "negative" result, but are given a numerical estimate ("1 of XX") of the probability of Down syndrome. These probability estimates may help aid further decision making by the patient.

Trial design issues include the population of patients studied (i.e., high risk or average risk) and the quality of follow-up to avoid verification bias. Verification bias refers to a problem in which the outcome status (Down syndrome or normal) is not assessed or is not available in certain patients. In the context of Down syndrome screening, spontaneous abortion is more likely in fetuses with chromosomal anomalies. Fetuses that miscarry may be more likely to be Down syndrome fetuses, and may be missed among those who have negative screening tests. Therefore, unless karyotyping is performed in all cases of spontaneous abortion or stillbirth, it is likely that a certain percentage of Down syndrome fetuses will go undetected. (2) Therefore, to avoid verification bias, it is important to have as complete a follow-up as possible of all pregnancy outcomes with karyotypic analysis on stillbirths and live births with dysmorphic features and phenotypic assessment of other live births.

Literature Review This policy was originally created in 2003 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period March 2008 through January 2010. For the first time in 2010, a search for studies on fetal nasal bone was conducted and included all major studies on this topic. Following is a summary of the literature to date.

First-Trimester Screening with Nuchal Translucency and Maternal (Biochemical) Markers
There are 3 large prospective, multicenter studies on the sensitivity of first-trimester screening that includes nuchal translucency measurements. The Serum, Urine, and Ultrasound Screening Study (SURUSS) study enrolled over 47,000 women, of whom 101 had fetuses with Down syndrome. (3) This study evaluated several tests in parallel, including first-trimester testing with nuchal translucency and maternal markers, the triple test, second-semester quadruple test, and a combined first- and second-trimester test (both with and without nuchal translucency). There were very high rates of verification, and adjustments were applied to account for miscarriages. Calculation of risk for all tests was done with a similar analytic methodology. There was no abnormal cutoff threshold for any measurement of nuchal translucency or maternal serum analyte, as all measurements were entered into the regression model as continuous variables. In a direct comparison of the first-trimester test to the triple test, at a threshold of 85% detection, the first-trimester test had a false-positive rate of 6.1%, and the triple test had a false-positive rate of 9.3%. The lower false-positive rate at the same sensitivity means that the first-trimester test had superior discriminative capacity. Setting the false-positive rate at 5% resulted in a sensitivity of 83%, which was superior to what was historically expected of the triple test. The study also evaluated nuchal translucency measurement alone. Its performance was considerably worse than either first-trimester testing or the triple test, with a false-positive rate of 20% at a diagnostic sensitivity of 85%.

The BUN study was also published in 2003, and evaluated first-trimester screening using the nuchal translucency and the same maternal markers (human chorionic gonadotropin and pregnancy-associated plasma protein A) as the SURUSS study. (4) Approximately 8,500 patients were enrolled, and 61 cases of Down syndrome were identified. Using a screening threshold of 1 in 270, 52 of 61 (85%) of Down syndrome cases were detected with a false-positive rate of 9.4%. If the threshold were changed to produce a false-positive rate of 5%, the detection rate was 78.7%. Taking into account possible biases due to miscarriages, the authors

calculated that second-trimester screening would have to be 75% sensitive to be equivalent to the 78.7% sensitivity they found for first-trimester screening.

Another large, prospective, multicenter study similar in design to the SURUSS study was published in 2005. (5) This was the First and Second Trimester Evaluation of Risk (FASTER) trial, conducted in the U.S. and sponsored by the National Institutes of Health (NIH). The study enrolled 38,167 women, of whom 117 had a fetus with Down syndrome. All women underwent first-trimester testing with nuchal translucency and maternal markers, and second-trimester quadruple screening. The study compared the results of each test, as well as stepwise sequential screening (results provided after each test analyzed), fully integrated screening (results only provided after all tests analyzed), and serum-integrated screening (similar to fully integrated but nuchal translucency results not included). At a threshold of 5% false-positive rate, the rate of detection of Down syndrome was 87% for first-trimester combined screening performed at 11 weeks, 63% for nuchal translucency alone at 11 weeks, 81% with second-trimester quadruple screening, 88% with serum-integrated screening, and 96% for fully integrated screening (first-trimester at 11 weeks). The detection rate of first-trimester screening was somewhat lower if performed after 11 weeks: 85% at 12 weeks and 82% at 13 weeks. Results of the FASTER trial provided further evidence that first-trimester combined screening was effective, but not nuchal translucency measurement alone, and that integrated first- and second-trimester screening provided higher detection rates.

Subsequent studies (6-9) have confirmed that combined first-trimester screening that includes nuchal translucency measurement and maternal serum markers is superior to nuchal translucency measurement alone. Studies continue to investigate the optimal approach to testing that balances the desires to maximize detection, minimize false-positive results, minimize unnecessary testing, and provide information to women as early in their pregnancies as possible. As stated, the SURUSS and FASTER studies have estimated the results of several approaches, including combination first-trimester testing only, stepwise sequential testing (results given after first trimester testing, move on to second trimester testing), and integrated screening (results given only after first and second trimester testing). A retrospective analysis of the prospectively collected FASTER data by Cuckle and colleagues introduced another screening approach, called “contingent screening.” (10) Initial risk was calculated from first trimester nuchal translucency measurement and maternal serum markers, and classified as positive (i.e., greater than 1 in 20), borderline (i.e., 1 in 30–1,500) and negative (i.e., less than 1 in 1,500). Women with positive tests were offered immediate prenatal diagnosis and those with borderline tests underwent second trimester quadruple screening and risks were recalculated. A final risk of greater than 1 in 270 was considered positive. This approach differs from stepwise sequential testing in that only women with borderline results continued to second-trimester testing. First-trimester testing identified 52 of 86 (60%) affected fetuses with a 1.2% false-positive rate (401 false-positive results). The final detection rate with the contingent approach was 91% with a 4.5% false-positive rate. Detection rates were similar with the stepwise approach (92% with 5.1% false-positive results) but substantially more women received second trimester testing, 31,868 with stepwise testing versus 7,360 with contingent testing. A limitation of the Cuckle et al. 2008 study (10) is that it was a retrospective analysis.

Several prospective studies evaluating a particular approach to combining first- and second-trimester screening results have been published. Wald and colleagues reported on use of the integrated screening strategy in practice. (11) Records from two London hospitals were reviewed for 15,888 women who presented in the first trimester and were screened. Ninety-eight percent accepted integrated screening and 94% of women completed both testing stages. The Down syndrome detection rate was 87%, consistent with an estimate of 89% predicted by SURUSS. The observed false-positive rate was 2.1%. In a follow-up to the BUN study, the sequential approach to screening was evaluated. (12) A first-trimester test result of greater than 1 in 120 risk was considered positive; these women were offered immediate diagnostic testing. Of the 7,392 women with a negative first-trimester screen, 4,145 underwent additional second-trimester screening that identified 6 of 7 (86%) affected fetuses among those tested, with a false-positive rate of 8.9%. To date, there does not appear to be consensus regarding which screening approach is optimal, and women may need to be offered several choices since individuals vary on their preferences for more immediate versus more accurate results.

Several studies have addressed whether women whose fetuses have large nuchal translucency measurements benefit from any additional screening tests or should move directly to diagnostic testing with chorionic villus sampling. A retrospective analysis of 36,120 patients in the prospective FASTER study, published in 2009, found no added benefit in waiting for serum screening results when nuchal translucency was 4.0 mm or greater, and minimal benefit when nuchal translucency was 3.0 mm or greater. (13) In this study, there were 32 (0.09%) fetuses with nuchal translucency of at least 4.0 mm. Among these 32 cases, the lowest final Down syndrome risk after including first-trimester serum markers was 1 in 8. Similarly, a retrospective study of 77,443 women in Quebec found that final combined first-trimester screening results were always positive in the 197 (0.3%) when nuchal translucency measurements were at least 4.0 mm. (14) A study from Australia conducted first-trimester screening on 76,813 women and identified an extremely large nuchal translucency (here defined as 6.5 mm or greater) in 120 cases. (15) Abnormal karyotypes were found in 89 of the 120 cases (74%).

An ongoing issue with nuchal translucency measurement is the possible variability of ultrasonographic interpretation. The Fetal Medicine Foundation in the U.K. has a training program that offers an Internet-based certificate of competency in nuchal translucency. (16) Continuing medical education courses in the U.S. are also available through the Fetal Medicine Foundation's U.S. affiliate. (17) Training and certification, along with ongoing quality control, an appropriate reference database of patients and use of statistical methodology, are necessary to produce optimal diagnostic results. Two recent studies with large sample sizes (18, 19) estimated the impact of measurement error on the results of first-trimester screening by taking actual screening results and artificially altering the nuchal translucency values. Both studies found that even small deviations in measurement of nuchal translucency affect the false-positive and false-negative rates. For example, in the Schmidt et al. study (19), which analyzed data from 10,116 pregnancies, underestimating the nuchal translucency by 0.5 mm increased the number of false-negative results from 12 to 20 (an increase of 66.7%) and decreased the number of false-positive results from 479 to 281 (a decrease of 41.3%). On the other hand, overestimating the nuchal translucency by 0.5 mm decreased the number of false negative results from 12 to 11 (a decrease of 8.3%) and increased the number of false-positive results from 479 to 1,149 (an increase of 140%). (19) Findings emphasize the importance of accurate measurement of nuchal translucency and potential value of combining nuchal translucency findings with maternal serum markers.

Fetal Nasal Bone

Performance of fetal nasal bone assessment

A systematic review by Rosen and colleagues for the U.S.-based Maternal Fetal Medicine Foundation Nuchal Translucency Oversight Committee identified 10 studies in a 2006 MEDLINE search on fetal nasal bone performance. (20) A total of 35,312 women underwent first-trimester ultrasound assessment of fetal nasal bone. The fetal nasal bone was successfully imaged in 33,314 (94.3%) of cases and could not be imaged in 5.7% of cases. There were 479 Down syndrome fetuses, a prevalence of 13.6 in 1,000. The authors note that this is 10 times the first-trimester incidence in the U.S., suggesting a high-risk population had been screened. The fetal nasal bone was absent in 310 of 479 (65%) Down syndrome cases and in 274 of 34,048 (0.8%) chromosomally normal cases.

One of the included studies, a subanalysis of the FASTER study, discussed above, involved a general population sample and had much lower rates of successful imaging than other studies. (21) Assessment of fetal nasal bone was added to the FASTER protocol during the last 7 months, but did not occur in all centers. A total of 6,324 women underwent fetal nasal bone sonography and pregnancy outcome data were available for 6228 (98.5%) of them. Sonographers failed to obtain an adequate view in 1,523 patients (24%). Among the 4,801 cases with adequate images of the fetal profile, the nasal bones were described as being absent in 22 (0.5%) of them. There were 11 identified cases of Down syndrome. Fetal nasal bone assessment did not identify any of these cases as potentially high risk. In 9 of the 11 cases (92%), the fetal nasal bones were judged to be present, and in 2 cases, were unable to determined. There were also 2 cases of trisomy 18; nasal bones were present in one and absent in the other. The FASTER investigators concluded that first-trimester fetal nasal bone sonography does not seem to have a role in general population screening for Down syndrome. Other researchers have commented on the lower rate of successful fetal nasal bone assessment in the FASTER analysis. The Rosen review article (20) noted that, although the sonographers were trained and experienced in

nuchal translucency measurement, they were new to fetal nasal bone assessment. Another review article by Sonek and colleagues states that the likely explanation for the FASTER findings is that their techniques were different from those used by others. (22)

One study was identified that directly compared the performance of fetal nasal bone assessment in unselected and selected populations. (23) This prospective study included a total of 7,672 pregnant women, 7116 of whom were at average risk and 510 at increased risk (more than 1 in 300) of Down syndrome based on age, family history, or previous pregnancy history. It was not possible to adequately assess the fetal nasal bones in 712 of 7,116 (10%) in a general population sample, and in 42 of 510 (8.2%) in a high-risk sample. A total of 35 cases of Down syndrome were identified, 23 in the selected group and 12 in the unselected group. Two Down syndrome cases in the selected group were excluded because there was not a satisfactory ultrasound examination. In the remaining cases, absent fetal nasal bones identified 10 of 21 (47.6%) Down syndrome cases in the selected population and 2 of 12 (16.7%) in the unselected group. An analysis including the 2 missing cases found that fetal nasal bone assessment was able to correctly identify 10 of 23 or 43.5% of Down syndrome cases. A logistic regression model including fetal nasal bone findings, as well as nuchal translucency and demographic factors, absence of fetal nasal bone was found to be an independent predictor of trisomy 21 in the selected pregnancies group, but not in the unselected pregnancies group.

Fetal nasal bone assessment in first-trimester screening programs
Several studies were identified that evaluated the diagnostic accuracy of first-trimester screening programs that included fetal nasal bone measurements as part of a comprehensive screening program. None of these was multicenter and none was conducted in the U.S.

Cicero and colleagues conducted a single-center prospective screening study in the UK. (24). Down syndrome screening including fetal nasal bone assessment was conducted in 21,074 singleton pregnancies at 11 to 13 weeks' gestation. Data from 20,418 (97%) women were available for analysis. Chromosomal abnormalities were detected in 253 of the pregnancies; this included 140 cases of Down syndrome. An adequate view of the fetal profile could not be obtained in 243 (1.2%) of cases. Of the 20,175 cases in which the fetal profile could be obtained (i.e., "successful" examination), the nasal bone was recorded as absent in 238 (1.2%) of cases and present in 19,937 (97.6%). Combined screening with nuchal translucency assessment and maternal serum markers achieved a detection rate of 90% at a fixed false-positive rate of 5%. With the detection rate fixed at 90%, the inclusion of nasal bone measurements using either screening strategy decreased the false-positive rate to 2.5%. In another analysis at a fixed false-positive rate of 5%, the inclusion of fetal nasal bone assessment of all women in the sample increased the detection rate to 93.6% at the 5% false-positive rate. The same increase in the detection rate, to 93.6%, was obtained when fetal nasal bone assessment was included only for women of intermediate risk (one in 51 to one in 1,000).

In a prospective study by Has and colleagues from Turkey, 2,080 women with singleton pregnancies underwent fetal nasal bone ultrasound by trained staff as part of first-trimester screening at 11 to 14 weeks' gestation. (25) Data were available for 1,926 (92.6%) of fetuses. The investigators then excluded 110 cases without known chromosomal abnormalities in which there was fetal or neonatal death, pregnancy termination, or survival with malformations. Among the remaining 1,816 pregnancies, the fetal nasal bone could not be evaluated in 9 (0.5%) of the women. Fetal nasal bone was judged to be absent in 10 (0.6%) cases and present in 1,791 (99.4%) of cases. It was absent in 3 of 9 (33.3%) fetuses known to have Down syndrome and 7 of 1,792 (0.4%) of chromosomally normal fetuses. The detection rate of first-trimester screening (nuchal translucency and maternal serum markers) was 8 of 9 (88.9%) affected fetuses with a false-positive rate of 3.6%, using a risk cut-off of one in 300. Incorporating the fetal nasal bone assessment did not change the detection rate, but decreased the false-positive rate from 0.6% to 3.0%.

A study conducted in Hong Kong was a retrospective analysis of 10,767 women who had been screened in a comprehensive first-trimester screening program. (26) The analysis compared several approaches to screening. Among the 10,854 fetuses with a known outcome, 32 had Down syndrome. In a screening approach that combined nuchal translucency assessment and maternal serum markers in this group, 27 (94%) of the

pregnancies would have been classified as high risk, 4 as low risk, and 1 as intermediate risk. The protocol included fetal nasal bone assessment of intermediate-risk pregnancies, with reclassification as high risk if the fetal nasal bone was absent. The one case classified as intermediate risk had an absent fetal nasal bone. In this study, too few cases were classified as intermediate risk to determine whether fetal nasal bone assessment in a contingent screening approach improves screening accuracy.

As with nuchal translucency measurement, there are possible issues around variability of fetal nasal bone interpretation and the need for adequate training and quality control. The review article by Rosen and colleagues states that mastering imaging of the nasal bone appears to be more difficult than mastering nuchal translucency measurement. (20) The Committee recommends that sonographers undergo training, gain hands-on experience, and submit images for external review before starting clinical acquisition, and they further recommend ongoing monitoring of nasal bone images locally by an experienced physician. The Fetal Medicine Foundation in the UK has an Internet-based certificate of competency in fetal nasal bone assessment; their website does not state how long this program has been available. (27)

Another issue is generalizability of nasal bone assessment to general clinical practice. The article by Rosen and colleagues for the Fetal Medicine Foundation Nuchal Translucency Oversight Committee reports that fetal nasal bone assessment studies have come primarily from a few specialized centers. Information on the performance of fetal nasal bone assessment in other settings is lacking. (20) Moreover, possible differences in findings using different ultrasound techniques or equipment have not been adequately explored. The Oversight Committee recommends further evaluation of nasal bone assessment in low-risk populations, and additional availability of adequately trained centers before nasal bone assessment is introduced into general practice. They also suggest considering a contingent screening strategy. The approach they suggest is similar to that used in the Sahota et al. study (26) from Hong Kong, discussed above, in which fetal nasal bone assessment is used only in cases that have a borderline risk determination by screening with nuchal translucency and maternal serum markers. If a contingency model were used, patients could be referred to centers with developed expertise, although the authors note that this may not be feasible or practical in all areas of the U.S.

Summary

Nuchal translucency There is sufficient evidence from two large prospective multicenter studies (SURUSS and FASTER) and several smaller studies that first-trimester screening for Down syndrome with measurement of fetal nuchal translucency and maternal serum markers is a reasonable approach and may be considered medically necessary. The SURUSS and FASTER studies also found that overall first-trimester screening with nuchal translucency alone is inferior to either first- or second-trimester combined screening. Recent data suggest that additional testing may not be necessary in those few cases when nuchal translucency is at least 4.0 mm due to the high likelihood of Down syndrome in these cases.

Fetal nasal bone assessment Studies have found a high rate of successful imaging of the fetal nasal bone and an association between absent nasal bone and the presence of Down syndrome in high-risk populations. However, there is insufficient evidence on the performance of fetal nasal bone assessment in average-risk populations. Of particular concern is the low performance of fetal nasal bone assessment in a subsample of the FASTER study conducted in a general population sample. Two studies conducted outside of the U.S. have found that, when added to a first-trimester screening program evaluating maternal serum markers and nuchal translucency, fetal nasal bone assessment can result in a modest decrease in the false-positive rate. Several experts in the field are proposing that fetal nasal bone assessment be used as a second stage of screening, to screen women found to be of borderline risk using maternal serum markers and nuchal translucency. Additional studies using this contingent approach are needed before conclusions can be drawn about its utility. In summary, given the uncertainty of test performance in average-risk populations and the lack of standardization in the approach to incorporating this test into a first-trimester screening program, detection of fetal nasal bone is considered investigational.

Technology Assessments, Guidelines and Position Statements

In January 2007, the American College of Obstetricians and Gynecologists (ACOG) released an updated practice bulletin that recommended that all women, regardless of age, be offered aneuploidy screening before 20 weeks' gestation. No single specific testing strategy was recommended. The recommendations state that first-trimester combined screening (nuchal translucency and maternal serum markers) is effective for testing for Down syndrome. They further state that fetal nasal bone assessment in the general population is controversial, and that additional testing standardization, training for physicians and quality-control programs are needed. (1)

Medicare National Coverage
No national coverage determination**.**

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[12] Recommendations from the Massachusetts Chapter of the American College of Obstetrics and Gynecology; David Elmer, MD, Jeffery Ecker, MD, and David Hagan, MD. Electric Blue Review 10/01.

[13] Based on the Blue Cross Blue Shield Association national policy 6.01.07, issued 7/99. The national policy is based on the 1994 TEC assessment that reviewed the following indications for transcranial Doppler:

- monitoring for vasospasm in patients with subarachnoid hemorrhage
- intraoperative assessment and monitoring of collateral blood flow and embolizations in patients undergoing carotid endarterectomy.
- evaluation of patients with transient ischemic attacks or cerebrovascular accidents for intracranial artery stenosis
- evaluation of patients who have sickle cell disease without symptoms of TIA or CVA for intracranial artery stenosis.

While the1994 TEC assessment concluded that for the first 2 indications above, transcranial Doppler met the TEC criteria and indications 3 and 4 did not, more recent randomized controlled trials reported on 130 children with sickle cell anemia and abnormal result on TCD. Abnormal TCD was defined as 200-cm per/sec in the internal carotid artery or the middle cerebral artery. 63 patients were randomized to receive transfusions in order to achieve target hemoglobin S concentration of less than 30% of total hemoglobin while 67 patients received standard care. The national policy noted that there was significant decrease in the incidence of stroke in the transfusion group, leading to premature termination of the trial. This trial did not address how long transfusion should be continued as a means of preventing stroke or at what intervals repeat TCD is warranted. Despite the positive results of the trial, chronic transfusion therapy presents its own set of risks that may limit enthusiasm for this approach. For example, treatment of iron overload will likely be required.

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[14]Recommendations from expert physicians Massachusetts General Hospital- Radiology Department; Electric Blue Review 1/02.

[15]Based on local Medicare guidelines. See also Medicare's website at http://207.37.244.64/lmrp/final/ne/00-4R2.html

[17] ICD-9-CM diagnoses codes that are covered for commercial products and for Medicare HMO Blue and Medicare PPO Blue when billed with CPT code 76645:

- (174.0-174.9) Malignant neoplasm of female breast
- (175.0-175.9) Malignant neoplasm of male breast
- (198.2) Secondary neoplasm skin of breast
- (198.81) Secondary malignant neoplasm of breast
- (217) Benign neoplasm of breast
- (233.0) Carcinoma in situ of breast
- (239.2) Neoplasm of unspecified nature of bone, soft tissue and skin
- (239.3) Neoplasm of unspecified nature of breast
- (610.0) Solitary cyst of breast
- (610.1) Diffuse cystic mastopathy
- (610.2) Fibroadenosis of breast
- (610.3) Fibrosclerosis of breast
- (610.4) Mammary duct ectasia
- (611.0) Inflammatory disease of breast
- (611.1) Hypertrophy of breast
- (611.2) Fissure of nipple
- (611.3) Fat necrosis of breast
- (611.4) Atrophy of breast
- (611.71) Mastodynia
- (611.72) Lump or mass in breast
- (611.79) Other sign and symptom in breast
- (611.81) Ptosis of breast
- (611.82) Hypoplasia of breast
- (611.83) Capsular contracture of breast implant
- (611.89) Other specified disorders of breast
- (611.9) Unspecified breast disorder
- (793.80) Abnormal mammogram, unspecified
- (793.81) Mammographic microcalcification
- (793.82) Inconclusive mammogram
- (793.89) Other abnormal findings on radiologic exam of breast
- (996.54) Mechanical complication due to breast prosthesis

[18] Based on the BCBSA national policy 6.01.14, Ultrasound for the Evaluation of Paranasal Sinuses, issued 3/2002.

Rationale

The diagnosis and management of disorders of the paranasal sinuses are the typical focus of a general otolaryngologist's practice. While most cases can be managed empirically, imaging of the sinuses may be required for equivocal or atypical presentations. Imaging options include plain film radiography, computed tomography (CT), magnetic resonance imaging (MRI), or ultrasonography, with CT scans considered the gold standard. Ultrasonography has been proposed as a convenient office-based alternative with the added advantage

of low radiation exposure and a better discriminator between mucosal thickening and fluid retention. However, a review of the English language literature did not identify any published studies that adequately explored the diagnostic capabilities of ultrasonography in comparison to other imaging options. For example, in a 1997 study, Haapaniemi and colleagues performed plain film radiography and ultrasound of the maxillary sinus on a series of 663 unselected school children ages 7 to 14 years old. (1) The plain film radiograph was considered the gold standard, and sinusitis was suggested if marked mucosal thickening or the presence of a fluid level or cyst was present. On ultrasonography, the presence of a back wall echo was considered an abnormal finding, suggesting chronic sinusitis. Discrepancies between the 2 studies occurred in 74 studies; the presence of a back wall echo on ultrasonography predicted positive x-ray finding with a sensitivity of 69%, while a negative ultrasonography predicted the absence of chronic sinusitis with a specificity of 98%. However, the results of these studies were not correlated with the children's symptoms, and considering that the interpretation of plain film x-rays, particularly the evaluation of mucosal thickening, has been controversial, this outcome is important. Other studies have reported the findings of ultrasonography of the paranasal sinuses in either asymptomatic patients (2) or those with known sinusitis (3), two groups that do not mimic its proposed clinical application.

2002-6 Update
A review of the literature based on the MEDLINE database for the period of 1999 through December 2005 did not identify any published peer-reviewed literature that addresses the limitations noted in the discussion here. Therefore, the policy statement is unchanged. In 2001, the American Academy of Pediatricians (AAP) published clinical practice guidelines for the management of sinusitis. (4) These guidelines note that the diagnosis of sinusitis is typically made clinically, based on the presence of upper respiratory symptoms that are either persistent or severe. Furthermore, these guidelines suggest that imaging studies are not necessary to confirm a diagnosis of clinical sinusitis in children under 6 years of age. For those under age 6, the need for radiographs as a confirmatory test of acute sinusitis is controversial. Computed tomography (CT) scanning is considered the gold standard of imaging techniques for evaluating the sinuses, but is only recommended for patients who are considering surgery. The AAP Clinical Practice Guidelines do not either discuss or recommend ultrasound of the paranasal sinuses in the diagnosis and management of sinusitis. The American Academy of Allergy, Asthma and Immunology published parameters for the diagnosis and management of sinusitis in 1998. (5) These parameters state that CT is the preferred imaging technique for preoperative evaluation of the paranasal sinus and that ultrasonography has "limited utility, but may be applicable in pregnant women and to determine the amount of retained secretions." Finally, the American College of Radiology published Appropriateness Criteria for sinusitis in the pediatric population. (6) Levels of appropriateness, ranging from 1–9, with 1 being the least appropriate, are assigned to different sets of clinical symptoms associated with sinusitis. These criteria also suggest that CT is the most appropriate imaging modality. For all 8 symptom complexes, ultrasonography was given a 1or 2 appropriateness rating.

2007 Update
A literature search performed using MEDLINE through July 2007 did not identify any published literature that would alter the policy statement noted above.

2008 Update
A literature search performed using MEDLINE through August 2008 did not identify any published literature that would alter the policy statement noted above.

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[19]Based on the NHIC-NE Local Medical Review Policy, *Non-Vascular Studies* (#01-R2-09). Effective 7-15-2002. www.medicarenhic.com

[21]Approved for coverage based on review by Medical Director, Medical Policy Administration in consultation with contracted OB/GYN physician specialist, 6/03. October 2006: OB/GYN MPG meeting and discussion with OB/GYN physician specialist; and final approval by Medical Director-Medical Policy Administration- the diagnosis of Vasa Previa (ICD-9-CM 663.53) added to the clinical indications for *medically necessary* OB Ultrasound.

[22] Evaluation for fetal malformations, once in nine months, for dates of service 3/15/02-12/31/02, covered billing procedure 76805 and ICD-9-CM diagnoses V28.3, V22.0, and V22.1. Effective 1/1/03 and after, due to a narrative change in procedure 76805 and new 2003 CPT codes, evaluation for fetal malformations covered billed with procedure 76811 and 76812 with these same diagnoses. Early pregnancy monitoring for history of infertility, for dates of service 8/1/02-12/31/02 covered billing procedure 76805, only, with diagnosis V23.0. Effective 1/1/03 and after, due to a narrative change in procedure 76805 and new 2003 CPT codes, early pregnancy monitoring for history of infertility covered billed with procedure 76801, 76802 or 76815 and diagnosis V23.0. Based on local expert's opinion.

[24] Centers for Medicare and Medicaid Services (CMS), CR5235, One-Time Only Ultrasound Screening for Abdominal Aortic Aneurysms (AAA) under Medicare Part B. Service as a result of a referral from an initial Preventive Physical Exam (IPPE); subject to certain eligibility/other limitations:

- Has a family history of abdominal aortic aneurysm
- Is a man age 65 to 75 years of age who has smoked at least 100 cigarettes in his lifetime
- Is a beneficiary, who manifests other risk factors in a category recommended for screening by the United States Preventive Services Task Force regarding AAA, as specified by the secretary of Health and Human Services, through the national coverage determination process.

[27]Based on the BCBSA National policy 2.02.16, Ultrasonographic Measurement of Carotid Intimal Medical Thickness as an Assessment of Subclinical Atherosclerosis, reviewed 7/2011.

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[28] ICD-9 CM diagnoses codes that are non-covered for commercial products only when billed with CPT code 76536, effective 4/2009:

- 461.0-461.9
- 473.0-473.9

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