Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 3/1/24**
(See policy history boxes for previous effective dates)

Title: Patient-Specific Cutting Guides and Custom Knee Implants

Description/Background

Patient-specific instrumentation has been developed as an alternative to conventional cutting guides, with the goal of improving both alignment and surgical efficiency. A number of patient-specific cutting guides are currently being marketed. Patient-specific guides are constructed with the use of preoperative 3-dimensional computed tomography or magnetic resonance imaging scans, which are taken 4 to 6 weeks before the surgery. The images are sent to the planner/manufacturer to create a 3-dimensional model of the knee and proposed implant. After the surgeon reviews the model of the bone, makes adjustments, and approves the surgical plan, the manufacturer fabricates the disposable cutting guides.

Regulatory Status

There are 8 commercially available patient-specific instrumentation systems for total knee arthroplasty. In 2008, the Smith & Nephew Patient Matched Instrumentation (now called Visionaire™ Patient Matched Instrumentation) was the first patient-specific cutting guide to receive Food and Drug Administration (FDA) clearance for marketing. Other systems cleared for marketing by the FDA are shown in Table 1 (FDA Product Code OOG).

Table 1. Patient-Specific Cutting Guides for Knee Arthroplasty

Device Name	Manufacturer	510(K) Number	Clearance Date
X-Psi	Orthosoft	K131409	9/13/2013
iTotal	Conformis	K120068	2/3/2012
Prophecy	Wright Medical Technology	K103598	10/17/2011
Trumatch	Depuy Orthopaedics	K110397	8/16/2011
Shapematch	Stryker	K110533	5/19/2011
Signature	Materialise	K102795	2/2/2011
Zimmer	Materialise	K091263	11/19/2009

Visionaire	Smith & Nephew	K082358	11/25/2008

Source: FDA: U.S. Food and Drug Administration.

Custom knee implants with their associated patient-specific cutting guides (iJig® instrumentation, ConforMIS) include:

- ConforMIS iTotal® Cruciate Retaining Knee Replacement System (ConforMIS)
- ConforMIS iTotal® Posterior Stabilized Knee Replacement System (ConforMIS)
- ConforMIS iUni® Unicondylar Knee Replacement System (ConforMIS)
- ConforMIS iTotal Hip system (ConforMIS).

FDA product codes: JWH, MBH, OIY, OOG

Medical Policy Statement

Use of custom implants or patient-specific instrumentation (e.g., cutting guides) for joint arthroplasty, including but not limited to use in unicompartmental or total knee arthroplasty, is considered experimental/investigational. There is insufficient evidence in the peer-reviewed medical literature to determine the effects of the technology on health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

27447 27599 L8699

Rationale

Clinical Context and Therapy Purpose

The purpose of patient-specific cutting guides in patients undergoing knee arthroplasty is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does patient-specific cutting guides improve the net health outcome in patients undergoing knee arthroplasty?

The following PICOs were used to select literature to inform this review.

Populations

The relevant population(s) of interest are individuals undergoing partial or total knee arthroplasty (TKA; also called knee replacement). Knee arthroplasty is an established treatment for relief from significant, disabling pain caused by advanced arthritis. This intervention is considered among the most successful medical procedures in the United States regarding the degree of improvement in functional status and QOL. As a result of the success of TKA, the increase in the aging population, and the desire of older adults to remain physically active, the incidence of TKA is increasing rapidly. It is projected that by 2030, the demand for knee replacement will approach 3.5 million procedures annually.(1)

Knee arthroplasty is performed by removing the damaged cartilage surface and a portion of underlying bone using a saw guided by templates and jigs. The cartilage and bone removed from the distal femur and proximal tibia are replaced with implants that recreate the surface of the joint. Patellar resurfacing may also be performed. Three-dimensional implant alignment (coronal, sagittal, axial) is considered to be critical for joint articulation and implant longevity. Less than 3° deviation from the rotational or mechanical axis, as determined by a straight line through the center of the hip, knee, and ankle on the coronal plane, is believed to minimize the risk of implant wear, loosening, instability, and pain.

Intervention

The therapy being considered is patient-specific instrumentation (e.g., cutting guides). The cutting guides are used to aid the surgeon intraoperatively in making the initial distal femoral and the initial proximal tibial bone cuts during TKA surgery. The cutting guides also establish the references for component orientations. The placement of conventional cutting guides (templates and jigs) is based on anatomic landmarks or computer navigation. Use of conventional instrumentation has been shown to result in malalignment of approximately one-third of implants in the coronal plane.(2) Computer-assisted navigation can significantly reduce the proportion of misaligned implants compared with conventional instrumentation but has a number of limitations including a lack of rotational alignment, increased surgical time, and a long learning curve. Also, no studies have demonstrated an improvement in clinical outcomes with computer-assisted navigation.

Comparators

For individuals undergoing knee arthroplasty, conventional cutting guides are currently being used for TKA (see intervention description).

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Commonly used instruments to measure these outcomes include the Knee Society Score (KSS), Oxford Knee Score, range of movement, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and visual analog scales.

The surrogate outcome measure of a reduction in malalignment may be informative to support improvement with the new technology. However, a reduction in the percentage of misaligned implants has not been definitively shown to result in improved clinical outcomes and is therefore not sufficient to demonstrate an improvement in clinical outcomes. Also, no long-term studies are currently available that could provide data on revision rates. It should also be noted that the design of these devices is evolving, and results from older studies may be less relevant for contemporary designs.

The proposed benefits of using patient-specific instrumentation during TKA includes improved alignment, decreased operative time, increased patient throughput, fewer instrument trays, reduced risk of fat embolism and intraoperative bleeding (no intramedullary canal reaming), shorter recovery, reduced postoperative pain, reduced revision rate, and reduced costs. However, the nonsurgical costs of the procedure may be increased due to the requirement for preoperative computed tomography or magnetic resonance imaging, preoperative review of the template, and fabrication of the patient-specific instrumentation. Also, the patient-specific template relies on the same anatomic landmarks as conventional TKA and does not take soft tissue balancing into account. Thus, evaluation of this technology should also address the reliability of the cutting guides and the need for intraoperative changes such as conversion to conventional instrumentation.

Component alignment and perioperative outcomes are short-term outcomes. Pain, function, and QOL should be measured in long-term studies (2 years or longer), in particular because component alignment is hypothesized to correlate to component longevity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

There are a number of systematic reviews on patient-specific instrumentation (PSI) for total knee arthroplasty (TKA). We focus on the most recent comprehensive, and relevant analyses. (See Table 2). Three of these reported functional outcomes in addition to measures of malalignment outcomes.(2-4)

Table 2. Comparison of Trials/Studies Included in Patient-Specific Instrumentation Meta-Analyses

Study[2]	Lin, et al. (2020)	Gong, et al. (2018)	Thienpoint, et al. (2017)	Mannan, et al. (2017)
Abane (2015)	●	●	●	●
Abane (2017)	●			
Abdel (2014)	●		●	
Anderl (2016)			●	●
Bali (2012)			●	
Barke (2013)			●	
Barrack (2012)			●	
Barrett (2014)			●	
Boonen (2012)			●	
Boonen (2013)	●	●	●	
Boonen (2016)	●	●		

Chareancholvanich (2013)	●	●	●	
Chen (2014)			●	
Chen (2015)			●	●
Chotanaphuti (2014)	●		●	
Cucchi (2018)	●			
Daniilidis (2014)			●	
De Vloo (2017)	●	●		
DeHann (2014)			●	
Ferrara (2015)			●	
Gan (2015)		●		
Hamilton (2013)	●	●	●	
Heyse (2014)			●	
Huijbregts (2016)	●	●		
Kassab (2014)			●	
Khuangsirikul (2014)		●		
Kosse (2018)	●	●		
Kotela (2014)	●	●	●	
Kotela (2015)	●	●	●	●
MacDessi (2014)			●	
Marimuthu (2014)			●	
Maus (2017)	●	●		
Molicnik (2015)	●		●	
Nabavi (2015)			●	
Nam (2016)			●	
Nankivell (2015)			●	
Ng (2012)			●	
Noble (2012)	●		●	
Nunley (2012)			●	
Parratte (2013)	●	●	●	
Pfitzner (2014)	●			●
Pietsch (2013)	●	●	●	
Renson (2014)			●	
Roh (2013)	●	●	●	
Schotanus (2018)	●			
Silva (2014)	●	●	●	
Stronach (2014)			●	
Thienpoint (2015)			●	
Van Leeuwen (2018)	●	●		
Victor (2014)		●	●	
Vide (2017)	●	●	●	
Vundelinckx (2013)	●	●	●	
Woolson (2014)	●	●	●	●
Yaffe (2014)			●	●
Yan (2015)	●	●	●	●
Zhu (2015)			●	

[1]Systematic review/meta-analyses across the columns.
[2]Primary studies across the rows.

Table 3. Meta-Analysis Characteristics

Study	Dates	Trials	N (Range)[a]	Designs	Outcomes

Lin et al (2020)[4]					
Gong et al (2018)[5]	1966-2018	23	2058 (40-180)	RCTs	Coronal, sagittal, axial malalignment >3°
Thienpont et al (2017)[3]	2011-2015	44	5822 (29-865)	RCTs and cohort	Coronal and sagittal malalignment >3°
Mannan et al (2017)[6]	2000-2015	8	828 (48-232)	RCTs and cohort	Functional outcomes

RCT: randomized controlled trial.

Table 4. Meta-Analysis Results for Malalignment Outcomes (>3 Degrees from Target)

Study	Trials	N (knees)	Malalignment (>3°)	RR	95% CI	p	I^2, %
Lin et al (2020)	17	1577	Hip-knee ankle angle	0.89	0.74 to 1.04	0.13	38
Gong et al (2018)[3]	14	1273	Hip-knee-ankle angle	0.94	0.72 to 11.24	0.68	41
	12	1137	Femoral/coronal plane	0.86	0.57 to 1.30	0.47	37
	12	1137	Tibial/coronal plane	1.36	0.75 to 2.49	0.31	46
	9	941	Femoral sagittal alignment	1.07	0.84 to 1.35	0.59	46
	10	989	Tibial/sagittal plane	1.31	0.92 to 1.86	0.13	57
Thienpont et al (2017)[4]	29	3479	Coronal mechanical axis	0.79	0.65 to 0.95	0.013	51
	13	1527	Tibial/sagittal plane	1.32	1.12 to 1.56	0.001	0
	15	1943	Femoral/coronal plane	0.74	0.55 to 0.99	0.043	32
	17	1983	Tibial/coronal plane	1.30	0.92 to 1.83	0.13	21.5

CI: confidence interval; RR: relative risk.

The key question we considered is whether differences in the number of outliers greater than 3° impacted functional outcomes. A meta-analysis by Mannan et al (2017) indicated that functional outcomes did not differ significantly when measured at up to two years after surgery (see Table 5).(6) More recent meta-analyses have shown mixed outcomes with regard to benefit. Thienpont et al (2017) showed an improvement in KSS functional score with patient specific instrumentation over conventional instrumentation, but there was no significant improvement in the KSS knee score.(3) In contrast, Lin et al (2020) showed a significant improvement in the overall KSS with patient specific instrumentation, but failed to show an improvement in the Oxford Knee Score.(4) The follow-up period for Lin et al was only 3 months and does not provide information on long-term outcomes.

Table 5. Meta-Analysis Results for Pain and Function Outcomes

Study	Trials	N (knees)	Functional Outcome Measures	FU, mo	MD	95% CI	p	I^2, %
Lin et al (2020)	3	337	KSS	3	-0.17	-0.33 to -0.02	0.02	0
	5	651	Oxford Knee Score	NR	0.07	-0.09 to 0.22	0.4	32
Thienport et al (2017)[3]	6	300	KSS functional score	16.7	4.3	1.5 to 7.2	0.003	NR
	6	300	KSS knee score	16.7	1.5	-0.3 to 3.3	0.093	NR

Mannan et al (2017)[6]	3	195	KSS functional score	24	-0.21	-9.31 to 8.88	0.96	82
	3	195	KSS knee score	24	0.90	-6.15 to 7.95	0.80	85
	5	244	Range of motion (deg)	3-24	3.72	-0.46 to 7.91	0.08	70
	3	118	Oxford Knee Score	3-12	-0.48	-1.83 to 0.86	0.48	0

CI: confidence interval; FU: follow-up; KSS: Knee Society Score; MD: mean difference. NR: not reported

Perioperative Outcomes

Systematic Reviews

Three of the meta-analyses included in this review reported perioperative outcomes (Table 6).(3-5) Total operative time was significantly shorter with patient specific instrumentation (PSI) in all studies, but the clinical significance of these differences is not clear. There was high heterogeneity among the studies that limits the application to clinical practice. Gong et al (2018) and Lin et al (2020) reported hospital length of stay and did not find a significant difference between PSI and conventional instrumentation groups. All 3 meta-analyses also showed a significant reduction in blood loss with patient specific instrumentation; however, there was high heterogeneity amongst the studies.

Table 6. Meta-Analysis Results for Perioperative Outcomes

Study	Operative Time (Minutes)	Blood Loss (mL)	Hospital LOS
Lin et al (2020)			
Total N	1404	300	543
Mean difference (95% CI); p-value	-0.36 (-0.67 to -0.04); p=0.03	-0.49 (-0.92 to -0.05); p=0.03	-0.10 (-0.27 to 0.07); p=0.24
I^2	88%	71%	33
Gong et al (2018)			
Total N	871	450	685
Mean difference (95% CI)	-7.35 (-10.95 to -3.75) p<0.0001	-83.42 (-146.65 to -20.18) p=0.010	-0.16 (-0.40 to 0.07) P=0.17
I^2	*78%*	*74%*	*19%*
Thienpoint et al (2017)			
Total N	3480	1251	
Mean difference (95% CI)	-4.4 (-7.2 to -1.7) p=0.002	-37.9 (-68.4 to -7.4)	
I^2	*94%*	*91%*	

CI: confidence interval; LOS: length of stay. MD: mean difference; NR: not reported.

Randomized Controlled Trials

Several RCTs have yet to be incorporated into available meta-analyses.(63-66) Table 7 highlights some of these RCTs. Additionally, several key RCTs included in available meta-analyses examine functional outcomes that are not evaluated by the meta-analyses.(17,33) These key trials include Boonen et al (2016) and Kosse et al (2017) and are also included in Table 7. Results for the trials included in Table 7 were consistent with previous studies as summarized in Table 6. All but 1 trial reported no significant differences between patient specific instrumentation and conventional intervention on measures of pain, function, and quality of life for up to 5 years (Table 8). Calliess et al (2017) reported significant outcomes with regard to KSS and WOMAC; however, follow-up did not extend beyond 1 year.(64)

Both Boonen et al (2016) and Kosse et al (2017) also reported on the outcome of pain measured by the visual analog score. Neither study reported a difference in pain improvement between groups. Boonen et al (2016) also reported no differences with regard to WOMAC index and EuroQoL-5D quality of life index. Kosse et al (2017) did not report any significant differences between groups for various outcomes, including the Kujala score (also referred to as the Patella score) and the Knee Injury and Osteoarthritis Outcome Score. The RCTs used a variety of patient specific instrumentation systems.

Table 7. Characteristics of Key RCTs of Patient Specific Instrumentation for TKA

Study; Trial	Countries	Sites	Dates	Participants	System (Manufacturer)
Hampton et al (2022)	UK	2	2013-2015	88	NexGen Knee (Zimmer)
Alvand et al (2017)	UK	1	2012-2014	46	Signature (Zimmer Biomet)
Kosse et al (2017)	The Netherlands	1	2012-2013	42	Visionaire (Smith & Nephew)
Calliess et al	Germany	2	2012-2013	200	Triathlon System (Stryker)
Boonen et al (2016)	The Netherlands	2	2010-2013	180	Materialise (Leuven)
Tammachote et al (2017)	Thailand	1	2012-2014	108	Visionaire (Smith & Nephew)

RCT: randomized controlled trial.

Table 8. Summary of Pain, Function, and Quality of Life Outcomes from Key RCTs

Study	KSS	Kujala	VAS Pain	OKS	EURO QOL-5D	KOOS	WOMAC
Hampton et al (2022)		NR	NR			NR	NR
N (FU)	77 Knees (5 years)			77 knees (5 years)	77 knees (5 years)		
PSI increase from baseline mean (SD)	94.5 (6.8)			40.8 (6.9)			
Conventional increase from baseline, mean (SD)	92.4 (7.1)			42.5 (7.4)			
p-valve	0.86			0.24	0.78		
Alvand (2017)							
N (FU)				45 (1 year)			
PSI, mean (range)				18.3 (4-31)			
Conventional, mean (range)				18.2 (5-31)			
P-value				NS			
Boonen (2016)							
N (FU)	163 (2 years)		163 (2 years)	163 (2 years)	163 (2 years)		163 (2 years)
PSI, mean (95% CI)	81.9 (78.1 to 85.8)		20.4 (14.4 to 26.5)	15.2 (13.1 to 17.2)	72.5 (68.2 to 76.7)		80.7 (76.3 to 85.0)
Conventional, mean (95% CI)	82.2 (78.6 to 85.8)		17.4 (12.2 to 22.6)	15.1 (13.1 to 17.1)	76.2 (71.9 to 80.5)		86.6 (83.4 to 89.8)
P-value	0.807		0.227	0.304	0.968		0.753

Calliess (2017)					
N (FU)	200 (1 year)				200 (1 year)
PSI	190 (SD 18)				13 (SD 16)
Conventional	178 (SD 17)				26 (SD 11)
P-Value	0.02				0.001
Kosse (2017)					
N (FU)	42 (1 year)	42 (1 year)	42 (1 year)	42 (1 year)	
PSI, median (range)	180 (135-200)	70 (44-100)	5 (0-40)	94 (50-100)	
Conventional, median (range)	175 (115-200)	62 (33-95)	11 (0-81)	81 (33-100)	
P-value	NS	NS	NS	NS	
Tammachote (2017)					
N (FU)					102 (2 years)
PSI, mean (SD)					5 (SD 6)
Conventional, Mean (SD)					4 (SD 6)
Mean difference (CI); p-value					1 (-1.8 to 3), P=0.62

CI: confidence interval; EuroQol-5D: standardized instrument as a measure of quality of life; FU: follow-up; KOOS: Knee Injury and Osteoarthritis Outcome Score; KSS: Knee Society Score; MD: mean difference; NR: not reported; NS: not significant; OKS: Oxford Knee Score; RCT: randomized controlled trial; SD: standard deviation; PSI: patient-specific instrumentation; VAS: Visual Analog Scale; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.

SUMMARY OF EVIDENCE

For individuals who are undergoing partial or total knee arthroplasty who receive patient-specific cutting guides, the evidence includes RCT's, comparative cohort studies, and systematic reviews of these studies. Relevant outcomes of interest are symptoms, functional outcomes, and quality of life. Results from the systematic reviews are mixed, finding significant improvements in some measures of implant alignment but either no improvement or worse alignment for other measures. The available systematic reviews are limited by the small size of some of the selected studies, publication bias, and differences in both planning and manufacturing of the patient specific instrumentation systems. Also, the designs of the devices are evolving, and some of the studies might have assessed now obsolete patient specific instrumentation systems. Available results from individual RCTs have not shown a benefit of patient-specific instrumentation systems in improving clinical outcome measures with follow-up currently extending out to 2 years. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Orthopaedic Surgeons

In 2016, the American Academy of Orthopaedic Surgeons published a guideline on the surgical management of osteoarthritis of the knee.(66) The guideline is supported by the American Society of Anesthesiologists and endorsed by several other organizations. The guideline recommends against the use of patient specific instrumentation for total knee arthroplasty, since strong evidence has not shown a difference in pain or functional outcomes when compared to conventional instrumentation. Additionally, moderate evidence has not shown a difference between patient specific and conventional instrumentation with regard to transfusions or complications.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 9.

Table 9. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01696552	Patient-specific Positioning Guides (PSPG) Technique Versus Conventional Technique in Total Knee Arthroplasty - a Prospective Randomized Study	109	Jan 2024
NCT02177227 [a]	Attune With TruMatch™ Personalized Solutions Instruments: A Prospective Randomized Controlled Trial Comparing Clinical and Economic Outcomes in Patients With a BMI Between 30 and 50	184	Aug 2024
Unpublished			
NCT02845206	Randomised Controlled Trial of Patient Specific Instrumentation vs Standard Instrumentation in Total Knee Arthroplasty	172	Feb 2020
NCT03148379[a]	A Multi-center, Prospective, Randomized Study Comparing Surgical and Economic Parameters of Total Knee Replacement Performed With Single-use Efficiency Instruments With Patient Specific Technique (MyKnee®) Versus Traditional Metal Instruments With Conventional Surgical Technique	231	Mar 2022
NCT02096393	A Prospective, Randomised Control Trial Assessing Clinical and Radiological Outcomes of Patient Specific Instrumentation in Total Knee Arthroplasty	72	June 2020

NCT: national clinical trial
[a]Denotes industry-sponsored or cosponsored trial.

Government Regulations

National:

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Local:

There is no local coverage determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 25, 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/18	12/12/17	12/12/17	Joint policy established
3/1/19	12/11/18		Routine maintenance
3/1/20	12/17/19		Routine maintenance
3/1/21	12/15/20		Routine maintenance
3/1/22	12/14/21		Routine maintenance
3/1/23	12/20/22		Routine maintenance (slp)
3/1/24	12/19/23		Routine maintenance (slp) Vendor managed: Turning Point

Next Review Date: 4th Qtr, 2024

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: PATIENT-SPECIFIC CUTTING GUIDES AND CUSTOM KNEE IMPLANTS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- *Duplicate (back-up) equipment is not a covered benefit.*