Saturation Biopsy for Diagnosis and Staging and Management of Prostate Cancer

Policy Number: 7.01.121  Last Review: 8/2017
Origination: 8/2006  Next Review: 2/2018

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for prostate saturation biopsy. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
Saturation biopsy, is considered investigational in the diagnosis, staging, and management of prostate cancer.

Considerations
Saturation biopsy is generally considered obtaining more than 20 biopsy tissue cores from the prostate in a systematic manner; it is occasionally defined as obtaining more than 18 biopsy tissue cores.

A CPT code for this procedure became effective in 2009:

55706: Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance.

This procedure may be reported with code 55700 (biopsy, prostate; needle or punch, single or multiple, any approach) when it is performed without stereotactic template guidance. This method may involve ultrasound guidance, which is reported with code 76942 (ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision, and interpretation).

For 2015, Medicare deleted codes G0417-G0419 and revised code G0416:

G0416: Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method
Prior to 2015, Medicare had the following specific HCPCS “G” codes for the pathology services associated with this service:

G0416: Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method, 10-20 specimens
G0417: Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method, 21-40 specimens
G0418: Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method, 41-60 specimens
G0419: Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method, greater than 60 specimens

Prior to 2015, a single G code would have been reported depending on the total number of specimens on which the laboratory performed pathology examinations (eg, for 50 specimens only G0418 is reported).

### Description of Procedure or Service

<table>
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<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
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</table>
| Individuals:  
- With suspected prostate cancer | Interventions of interest are:  
- Initial saturation biopsy  
- Repeat saturation biopsy | Comparators of interest are:  
- Standard biopsy | Relevant outcomes include:  
- Overall survival  
- Disease-specific survival  
- Test accuracy  
- Treatment-related morbidity |

| Individuals:  
- With prostate cancer who are potential candidates for active surveillance | Interventions of interest are:  
- Saturation biopsy | Comparators of interest are:  
- Standard biopsy | Relevant outcomes include:  
- Overall survival  
- Disease-specific survival  
- Test accuracy  
- Treatment-related morbidity |

Saturation biopsy of the prostate, in which cores are obtained than by standard biopsy protocol, has been proposed in the diagnosis (for initial or repeat biopsy), staging, and management of patients with prostate cancer.

For individuals who have suspected prostate cancer who receive initial saturation biopsy or repeat saturation biopsy, the evidence includes randomized and nonrandomized diagnostic accuracy studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and treatment-related morbidity. A 2013 systematic review found higher rates of cancer detection with saturation biopsy than extended biopsy overall, but in the subgroup of men with prostate-specific antigen (PSA) levels less than 10 ng/mL, the degree of difference was small and possibly not clinically significant. The use of saturation biopsy as a repeat biopsy after prior negative biopsies in men with persistent clinical suspicion of prostate cancer appears to increase the detection rate of cancer, particularly in the anterior zones. However, evidence is lacking as to whether this leads to improved health outcomes, including the possibility of detecting clinically insignificant cancers, which could lead to unnecessary treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have prostate cancer and are potential candidates for active surveillance who receive saturation biopsy, the evidence includes 2 nonrandomized comparative studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and treatment-related morbidity. Both studies retrospectively compared standard biopsy and saturation biopsy for selecting patients for active surveillance; neither found that saturation biopsy improved the ability to select patients. In 1 study, biopsy method was not a significant predictor of upstaging and, in the other study, biopsy method was not significantly associated with selecting patients with a high Gleason score. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2014 supported the investigational policy statement.

**Background**

Prostate cancer is a common cancer and is the second leading cause of cancer-related deaths in men in the U.S. The diagnosis of prostate cancer is made by biopsy of the prostate gland. The approach to biopsy has changed over time, especially with the advent of prostate-specific antigen (PSA) screening programs that identify cancer in prostates that are normal to palpation and to transrectal ultrasound. For patients with an elevated PSA level but with a normal biopsy, questions exist about subsequent evaluation, since repeat biopsy specimens may be positive for cancer in a substantial percentage of patients.

In the early 1990s, use of sextant biopsies involving 6 random, evenly distributed biopsies became the standard approach to the diagnosis of prostate cancer. In the late 1990s, as studies showed high false-negative rates for this strategy (missed cancers), approaches were developed to increase the total number of biopsies and to change the location of the biopsies. While there is disagreement about the optimal strategy, most would agree that initial prostate biopsy strategies should include at least 10–14 cores. Additional concerns have been raised about drawing conclusions about the stage (grade) of prostate cancer based on limited biopsy material. Use of multiple biopsies has also been discussed as an approach to identify tumors that may be eligible for subtotal cryoablation therapy.

At present, many practitioners use a 12 to 14 core “extended” biopsy strategy for patients undergoing initial biopsy. This extended biopsy is done in an office setting and allows for more extensive sampling of the lateral peripheral zone; sampling of the lateral horn may increase the cancer detection rate by approximately 25%. (1)

Another approach to increase the number of biopsy tissue cores is use of the “saturation” biopsy. In general, saturation biopsy is considered as more than 20 cores taken from the prostate, with improved sampling of the anterior zones of the gland, which may be undersampled in standard peripheral zone biopsy strategies and may lead to missed cancers. Saturation biopsy may be performed transrectally or with a transperineal approach; the transperineal approach is generally performed as a stereotactic template-guided procedure with general anesthesia.
In addition to diagnosis of prostate cancer, some have suggested that saturation biopsy could be a part of active surveillance (a treatment approach for men with prostate cancer that involves surveillance with PSA, digital rectal exam, and routine prostate biopsies in men whose cancers are small and expected to behave indolently). Saturation biopsy has the potential to more accurately identify tumor grade compared with standard biopsy.

**Rationale**
This evidence review was created in October 2009 and has been updated regularly with literature reviews of the MEDLINE database, most recently through June 10, 2016.

**Diagnosis: Initial or Repeat Saturation Biopsy**
To evaluate the impact of saturation biopsy on the net health outcome, studies are needed that compare rates of clinically significant prostate cancers detected using saturation biopsy versus other biopsy methods. Change in detection rate alone is not sufficient for determining the impact of saturation biopsy on health outcomes compared with other biopsy methods. With higher detection rates, there is the possibility of detecting clinically insignificant cancers, which could lead to unnecessary treatment. In addition, ideally studies would evaluate the impact of saturation biopsy on health outcomes such as disease progression or mortality.

**Initial Saturation Biopsy**
The literature consists of studies reporting prostate cancer detection rates or diagnostic yields as the primary outcome. These data are summarized in a 2013 systematic review and meta-analysis by Jiang et al on the utility of an initial transrectal saturation biopsy compared with an extended biopsy strategy.² A total of 8 studies (total N=11,997 participants) met eligibility criteria (ie, compared the 2 biopsy strategies on initial biopsy). Two of the studies were randomized controlled trials (RCTs), 1 used a paired design, and 5 were nonrandomized trials. Overall, prostate cancer was diagnosed in 2328 (42.4%) of 5486 men who underwent saturation biopsy compared with 2562 (39.3%) of 6511 men who had extended biopsy. The detection rate was statistically significantly higher in the saturation biopsy group (risk difference [RD], 0.004; 95% confidence interval [CI], 0.01 to 0.008; p=0.002). When only the higher quality studies were included in the meta-analysis (ie, the RCTs and prospective paired design), the detection rate remained statistically significantly higher with saturation biopsy (RD=0.03; 95% CI, 0.01 to 0.05; p=0.01). Subgroup analysis found that the difference in detection rates between saturation and extended biopsy strategies was limited to the subgroup of men with prostate-specific antigen (PSA) levels less than 10 ng/mL. Within this group, prostate cancer was diagnosed in 998 (38%) of 2597 men who had saturation biopsies and 1135 (34%) of 3322 men with extended biopsies (RD=0.04; 95% CI, 0.01 to 0.07; p=0.002). Although the analysis included subgroup analyses on individual risk factors such as PSA level, it did not differentiate between detection of lower and higher risk prostate cancers. In
addition, differences in health outcomes (eg, progression-free survival, overall survival) were not reported.

After the systematic review was published, a 2014 retrospective nonrandomized study by Li et al reviewed data on 438 men who received an initial saturation biopsy and 3338 men who had an initial extended prostate biopsy. In an analysis stratified by PSA values, there was a statistically significantly higher rate of prostate cancer detection using a saturation biopsy strategy in men with a PSA level less than 10 ng/mL. Detection rates among men with PSA level less than 4 ng/mL were 47.1% (40/85) with saturation biopsy and 32.8% (288/878) with extended biopsy (p=0.008). Rates among men with PSA levels between 4 ng/mL and 9.9 ng/mL were 50.9% (144/283) with saturation biopsy and 42.9% (867/2022) with extended biopsy (p=0.011). There was no statistically significant difference in detection rates between groups when PSA levels were greater than 10 ng/mL. Detection rates at PSA levels greater than 10 ng/mL were 60% (42/70) with saturation biopsy and 61% (267/438) with extended biopsy (p=0.879).

A related 2014 study by Li et al evaluated the potential benefit of saturation biopsy as the initial prostate biopsy strategy by examining the yield of repeat saturation biopsy in men with initial negative findings by either saturation or extended prostate biopsy. A total of 561 men were included in the study; the initial strategy was saturation biopsy in 81 men and extended biopsy in 480 men. In all cases, saturation biopsy was used for the first repeat biopsy. The overall prostate cancer detection rates were 19.8% in the group with initial saturation biopsy and 34.8% in the group with initial extended biopsy (p=0.008). Low-risk prostate cancer was defined using the Epstein criteria; ie, Gleason score of 6 or less, PSA density of 0.15 g/mL per gram or less, fewer than 3 positive cores, and more than 50% cancer involvement in a single core. The number of intermediate- and/or high-risk prostate cancers (ie, not low-risk) identified at first repeat biopsy was 4 (4.9%) of 81 in the initial saturation biopsy group and 85 (17.3%) of 490 in the initial extended biopsy group (p=0.048). The statistically significantly lower prostate cancer detection rate among men who initially underwent saturation biopsy suggests that initial saturation biopsy may be less likely to miss prostate cancer than extended biopsy, and, in this study, prostate cancer diagnosed by repeat saturation after negative initial saturation biopsy was more likely to be clinically insignificant. However, the study indirectly evaluated the initial biopsy, and the number of events in men who underwent an initial saturation biopsy was relatively small.

**Section Summary: Initial Saturation Biopsy**

Studies on saturation biopsy as the initial prostate biopsy strategy were summarized in a 2013 systematic review of 8 studies, 2 of which were RCTs. The prostate cancer detection rate was significantly higher in men with saturation biopsy than with standard biopsy. In a subgroup analysis, the systematic review found that the higher detection rate was limited to men with PSA levels less than 10 ng/mL. Health outcomes (eg, survival rate) were not reported. Although several studies were published after the systematic review, none showed that
initial saturation biopsy detects more clinically significant cancers and none reported progression or survival outcomes.

**Repeat Saturation Biopsy**

In 2006, Eichler et al published a systematic review of cancer detection rates and complications of various prostate biopsy schemes. They pooled data that compared various extended biopsy schemes for studies involving 20,698 patients. The authors concluded that prostate biopsy schemes consisting of 12 cores that add laterally directed cores to the standard sextant scheme seem to have the right balance between the cancer detection rate and adverse events, and that taking more than 12 cores added no significant benefit.

Representative studies of saturation biopsy in repeat prostate biopsies follow. These studies focused on cancer detection rates and did not report health outcomes (eg, overall survival, progression-free survival).

Mabjeesh et al reported on a high-risk group of men with at least 2 previous negative transrectal biopsies who then underwent transperineal template-guided saturation biopsy. Prostate cancer was detected in 24 (26%) of the 92 patients, predominantly in the anterior zones. A median of 30 cores was taken in the saturation biopsies. Gleason scores of 7 or higher were detected in 11 (46%) of the diagnosed men. Most tumors (83.3%) were found in the anterior zones of the gland, with a significantly higher number of positive cores versus the posterior zones (mean, 4.9 vs 1.5, p=0.015).

Lee et al evaluated the role of transrectal saturation biopsy for cancer detection in men with high-grade prostatic intraepithelial neoplasia (HGPIN) diagnosed by extended biopsy. From 1999 to 2009, 314 men had at least 1 or more repeat biopsies due to the presence of exclusive HGPIN (without any other pathologic finding) in a previous extended biopsy. They were divided into 2 groups according to the initial follow-up biopsy scheme; 178 men were followed using a second standard extended biopsy scheme, and 136 were followed using the saturation biopsy scheme. In the standard repeat biopsy group, 35 (19.7%) of 178 men had cancer on initial repeat biopsy. In the saturation biopsy group, 42 (30.9%) of 136 had cancer on initial repeat biopsy (overall, p=0.04). Multivariate analysis demonstrated that the biopsy scheme on repeat biopsy was an independent predictor of prostate cancer detection (odds ratio, 1.85; 95% CI, 1.03 to 3.29), exclusive of age, PSA level, days from initial biopsy, digital rectal exam (DRE) status, and multifocal prostatic epithelial neoplasia. Pathologic findings on repeat biopsies demonstrated similar Gleason grades, regardless of biopsy technique: a Gleason score of 6 was present in 74.3% and 73.1% of specimens in the standard and saturation schemes, respectively. The presence of a Gleason score of 8 or higher was 8.6% and 9.5%, respectively.

Zaytoun et al reported the results of a prospective, nonrandomized comparative study of extended biopsy versus office-based transrectal saturation biopsy in a repeat biopsy population. After an initially negative biopsy, 1056 men underwent either a repeat 12- to 14-core biopsy (n=393) or a 20- to 24-core repeat biopsy
(n=663) at the discretion of the attending urologist’s practice pattern. Indications for second biopsy included a previous suspicious pathologic finding and/or clinical indications such as abnormal DRE, persistently increased PSA level, and PSA level increasing more than 0.75 ng/mL annually. Prostate cancer was detected in 29.8% (n=315) of repeat biopsies. The saturation biopsy group had a detection rate of 32.7% versus 24.9% in the extended biopsy group (p=0.008). Of the 315 positive biopsies, 119 (37.8%) revealed clinically insignificant cancer (defined as Gleason sum <7, total of ≤3 positive cores, and maximum of ≤50% of cancer in any positive core). There was a trend toward increased detection of clinically insignificant cancer detection in the saturation (40.1%) versus the extended biopsy (32.6%) cases (p=0.02).

**Section Summary: Repeat Saturation Biopsy**
Several studies have compared saturation and standard prostate biopsies in the repeat biopsy setting and have found significantly higher detection rates with saturation biopsy. However, at least 1 study found that about one-third of the positive findings with saturation biopsy were clinically insignificant cancer. Moreover, studies of saturation biopsy as the repeat prostate biopsy strategy focused on cancer detection rates and did not report health outcomes (eg, progression or survival).

**Active Surveillance**
Several studies have evaluated the accuracy of saturation biopsy for identifying patients who might be suitable candidates for active surveillance. In 2013, Linder et al reviewed data on 500 consecutive patients who underwent standard template prostate biopsy (12 cores) or saturation biopsy (at least 18 cores) before radical prostatectomy. They identified 218 patients who would have been candidates for active surveillance. Criteria were Gleason score no greater than 6, clinical stage T1 or T2a, PSA level less than 10 ng/mL, and involvement of no more than 33% of cores. Among these 218 patients, 124 had undergone standard biopsy and 94 underwent saturation biopsy. In a multivariate analysis, biopsy method was not a significant predictor of upstaging on analysis of pathologic findings (p=0.26). In addition, the 5-year biochemical failure-free survival rates (defined as PSA level at least 0.4 ng/mL) did not differ significantly in the 2 groups: rates were 97% for standard biopsy and 95% for saturation biopsy (p=0.11).

In 2016, Quintana et al compared the utility of 12-core biopsy and saturation biopsy (18-33 cores; median, 20 cores) in 375 patients for accurately determining the Gleason score. The authors stated that patients with Gleason scores of 4 or higher were generally not considered candidates for active surveillance. Gleason score was confirmed by pathologic analysis of prostate specimens. For detecting a high Gleason grade (ie, ≥4), there were no statistically significant differences in the sensitivity, specificity, negative predictive value, or positive predictive value of 12-core versus saturation biopsies. The areas under the receiver operating curve were 0.82 for saturation biopsy and 0.84 for 12-core biopsy (p value not reported).
**Adverse Effects**
A 2016 study by Pepe and Pennisi reported prospectively on rates of erectile dysfunction (ED) following prostate biopsy. A total of 1050 men were evaluated; only the 560 men with benign histology and normal sexual activity were included in the analysis. Among these 560 men, 350 (62.5%) had extended biopsy (18 cores), 110 (19.5%) had saturation biopsy (28 cores), and 100 (18%) had saturation plus magnetic resonance-guided biopsy (32 cores). ED was measured using the 5-item version of the International Index of Erectile Function (IIEF-5) at baseline and 1, 3, and 6 months postbiopsy. There were no significant differences at any of the follow-up time points in the proportion of patients free from ED, with mild ED or with mild-to-moderate ED; no patients had severe ED.

Previously, in 2013, Pepe and Aragona reported more broadly on morbidity after transperineal prostate biopsies with different numbers of cores. The study included 3000 patients, of whom 915 (30.5%) underwent 12 needle cores, 1330 (48.5%) underwent 18 needled cores, and 630 (21%) underwent more than 24 needle cores. Biopsy-related complications were evaluated 15 to 20 days postprocedure. Complication rates significantly increased as the number of cores increased. Rates were 31.5% with 12 cores, 41.8% with 18 cores, and 57.4% with more than 24 cores (p=0.001). Sepsis was not reported in any patient.

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in Jun 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

**Summary of Evidence**
For individuals who have suspected prostate cancer who receive initial saturation biopsy or repeat saturation biopsy, the evidence includes randomized and nonrandomized diagnostic accuracy studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and treatment-related morbidity. A 2013 systematic review found higher rates of cancer detection with saturation biopsy than extended biopsy overall, but in the subgroup of men with prostate-specific antigen (PSA) levels less than 10 ng/mL, the degree of difference was small and possibly not clinically significant. The use of saturation biopsy as a repeat biopsy after prior negative biopsies in men with persistent clinical suspicion of prostate cancer appears to increase the detection rate of cancer, particularly in the anterior zones. However, evidence is lacking as to whether this leads to improved health outcomes, including the possibility of detecting clinically insignificant cancers, which could lead to unnecessary treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

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of upstaging and, in the other study, biopsy method was not significantly associated with selecting patients with a high Gleason score. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received through 3 physician specialty societies and 3 academic medical centers while this policy was under review in 2014. There were 5 responses from 1 specialty society, 4 responses from another, and 1 from the third, for a total of 10 specialty society responses. Most reviewers stated that saturation biopsy is considered investigational and did not think that saturation biopsy in patients with 2 prior negative biopsies and persistently rising PSA level is considered medically necessary. Clinicians proposed various options that could be used in the situation of prior negative biopsies and rising PSA level: there was no consensus on the best alternative approach. Suggestions included magnetic resonance imaging (MRI) with transrectal ultrasound, multiparametric MRI, and 3T pelvic MRI. There was near consensus that there is insufficient evidence to support use of any of these techniques in the situation being considered.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network Guidelines
National Comprehensive Cancer Network guidelines (v.2.2016) on prostate cancer early detection state that routine use of advanced biopsy techniques, including saturation biopsy, is not recommended for initial biopsy. However, based on emerging evidence, the guidelines also state that saturation biopsy can be considered for “very high-risk” men with previous negative biopsies. The newer evidence cited in the guidelines is largely on a low risk of sepsis with men biopsied with the transperineal approach compared with the transrectal approach.

American Urological Association
The 2013 American Urological Association guideline on the early detection of prostate cancer does not mention saturation biopsy.

U.S. Preventive Services Task Force Recommendations
The 2012 U.S. Preventive Services Task Force recommendation for prostate cancer screening does not address saturation biopsy. This recommendation is currently being updated.
Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References

Billing Coding/Physician Documentation Information
55706 Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance
G0416 Surgical pathology, gross and microscopic examination for prostate needle biopsy, any method.
ICD-10 Codes
C61 Malignant neoplasm of prostate
D07.5 Carcinoma in situ of prostate
D40.0 Neoplasm of uncertain behavior of prostate

For 2015, Medicare deleted codes G0417-G0419 and revised code G0416: Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method

Prior to 2015, a single G code would have been reported depending on the total number of specimens on which the laboratory performed pathology examinations (eg, for 50 specimens only G0418 is reported).

This procedure may be reported with code 55700 (biopsy, prostate; needle or punch, single or multiple, any approach) when it is performed without stereotactic template guidance. This method may involve ultrasound guidance, which is reported with code 76942 (ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision, and interpretation).

The Category III code, 0137T, was deleted effective 1/1/2009.

Additional Policy Key Words
N/A

Policy Implementation/Update Information
8/1/06 New policy, considered investigational.
2/1/07 No policy statement changes.
8/1/07 No policy statement changes.
2/1/08 No policy statement changes.
8/1/08 No policy statement changes.
2/1/09 Coding updated; remains investigational.
8/1/09 No policy statement changes.
2/1/10 No policy statement changes; remains investigational. Policy renumbered from 2.04.500 to 7.01.121. Policy title changed from Prostate Saturation Biopsy to Saturation Biopsy for Diagnosis and Staging of Prostate Cancer.
8/1/10 No policy statement changes.
2/1/11 No policy statement changes.
8/1/11 No policy statement changes.
2/1/12 No policy statement changes.
8/1/12 No policy statement changes.
2/1/13 No policy statement changes.
8/1/13 No policy statement changes.
2/1/14 “Taking more than 20 core tissue samples at one time” removed from policy statement; guidance on this issue added to Description.
8/1/14 “Taking more than 20 core tissue samples at one time” added to Considerations.
2/1/15 No policy statement changes.
3/1/15 No policy statement changes.
5/1/15 Updated HCPCS codes. No policy statement changes.
2/1/16 No policy statement changes.
8/1/16 No policy statement changes.
2/1/17 Policy title changed to Saturation Biopsy for Diagnosis, Staging, and Management of Prostate Cancer. No policy statement changes.
8/1/17 No policy statement changes.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating healthcare providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.