

Ü Instructions for Use

Collagen Crosslinks and Biochemical Markers of Bone Turnover (for Kentucky Only)

Policy Number: CS021KY.05 Effective Date: April 1, 2024

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Related Policies

None

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

For additional information, refer to the <u>Kentucky Revised Statute (KRS) 304.17A-263</u>: <u>Coverage Under Health Benefit Plan for</u> <u>Biomarker Testing</u>.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

СР	T Code	Description
8	2523	Collagen cross links, any method

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U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA regulates commercially marketed tests and test systems such as bone markers and categorizes these test systems to one of three Clinical Laboratory Improvement Act (CLIA) of 1988 regulatory categories (i.e., waived, moderate, or high) based on their potential risk to public health. Commercially marketed tests that have received 510(k) marketing clearance can be accessed through the 510(k) database (search by manufacturer or test system name) or through the CLIA database search by

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manufacturer, test system, or analyte name). Laboratories that use their own tests but do not market the kits to others are subject to the standards of the Clinical Laboratory Improvement Act (CLIA), but not to FDA marketing regulations.

Information was not identified regarding FDA-approved osteoporosis treatments and the use of biochemical markers in the diagnosis of osteoporosis, or in the selection, dosing, or administration of these drugs. In addition, the FDA consumer-focused website publication on osteoporosis does not include biochemical markers in its list of diagnostic tests. For additional information refer to: <u>https://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118551.htm</u>. (Accessed October 18, 2023)

References

Kentucky General Assembly, Kentucky Revised Statutes, (KRS) 304_17A_263. Available at: <u>https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=54217</u>. Accessed October 18, 2023.

Policy History/Revision Information

Date	Summary of Changes
04/01/2024	 Coverage Rationale Replaced coverage guidelines with instruction to refer to <i>Kentucky Revised Statute (KRS) 304.17A-263: Coverage Under Health Benefit Plan for Biomarker Testing</i> for additional information
	 Supporting Information Updated <i>References</i> section to reflect the most current information Removed <i>Description of Services</i> and <i>Clinical Evidence</i> sections Archived previous policy version CS021KY.04

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual[®] for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual[®] does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.