

Labor and Industries’ responses to public comments on the proposed  
Clinical Guidance for Evaluating Beryllium Sensitization and Chronic Beryllium Disease

**Quote** from the guidance to which most commenters expressed concern: “Claims in which the diagnosis of chronic beryllium disease is contended in the absence of positive BeLPTs that meet the requirements of section two under beryllium sensitization, will be examined by L&I through a separate exception process.”

Comment from:	Comment	Response
<p><b>Kris Tefft</b>, Executive Director, WA Self-insurers’ Association</p>	<p>Concerned we will accept claims for CBD without having objective findings and positive BeLPT tests. If we do this, it will conflict with occupational disease statute. Believes standards and process under which these claims will be evaluated are not clear, transparent, and in accordance with state law. Need to define “separate exception process” and ensure it’s lawful, or delete it altogether.</p>	<p>We concur that the referenced passage needs to be made clear. The intent is not to allow CBD in the absence of objective findings, and certainly not to allow a diagnosis that does not meet the definition of RCW 51.08.140. We have amended the guidance to make it clear that with CBD, there is sufficient published consensus medical opinion and no opposing evidence to suggest that <u>on rare occasions</u>, an individual may have a clinical presentation <u>and</u> objective findings that support the diagnosis of CBD on a more-probable-than-not basis, yet still have a negative BeLPT. The guidance has been amended to state that, should this rare circumstance occur, four objective criteria must be met for a case of CBD to be accepted on a claim. It also deleted the reference to a separate exception process for determining this. Such cases would benefit from evaluation by clinical experts at a Center for Chemically Related Illness (CRI), as would other complex CRI claims.</p>
<p><b>Gregory Jones</b>, Assist. Manager for Business and Financial Operations, CFO, Richland Operations Office</p>	<p>Has same concerns as Kris Tefft.</p>	<p>Same response as above.</p>
<p><b>Lawrence Mann</b>, Trial Attorney with Wallace Klormann, Lake Oswego</p>	<p>Objects to need for further diagnostic criteria, as it’s well established; concerned additional rules are not needed. “It is troublesome that OMD intimates a need for further clarification as to the diagnostic criteria or the legal standard when no showing of such need has been proffered.” Should be evaluated same as any other occ disease. Also has same objection as Kris Tefft and worried we’re trying to create a lesser standard of compensability that would conflict with RCW 51.08.140</p>	<p>There has been no mention of, and there is no intention to put this in rule. Making prudent evidence-based clinical and adjudicative decisions about beryllium sensitization and disease requires that nurses, physicians, and consultants who provide opinions about claims have an easy to follow summary of the criteria that are critical to making accurate diagnoses. After consulting with several beryllium exposure specialists and authors who have published the evidence, there is agreement that having these diagnostic criteria in a guidance document is a valuable tool for making the appropriate decisions for injured workers.</p>

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<p><b>Phil Valdens</b>, Penser, Richland, WA</p>	<p>Has the same concerns as Kris Tefft.</p>	<p>Same response as above.</p>
<p><b>Calin Tebay</b>, Beryllium Health Advocate/sitewide support, Hanford Beryllium Program</p>	<p><b>Makes four key points:</b></p> <ol style="list-style-type: none"> <li>1. Most workers were exposed without ever knowing they were in a Be contaminated area and no monitoring or data sampling is available so claims are denied for not being work-related. Even with IMEs, they're denied because of no documented exposure.</li> <li>2. Same concern as Kris Tefft on opaque and unknown exception process – needs to be explained.</li> <li>3. Number of sarcoidosis cases are rising and many workers have diagnosis of both sarcoidosis and CBD; BeLPT tests are negative but “other defining test results are apparent that diagnose CBD.” All Hanford workers with sarcoidosis are determined to be “Beryllium <u>Affected</u> Workers” and are restricted from their normal job duties, which can end their careers.”</li> <li>4. The Hanford site medical director “identifies individuals through consistent monitoring programs.” The Be affected workers are “sent to Off-Site medical evaluations for surveillance/diagnosis/treatment.” Then same as #3: Hanford medical director diagnoses sarcoidosis, classifies them as a Be affected worker, restricted from job, considers it work-related, but claims are denied.</li> </ol>	<ol style="list-style-type: none"> <li>1. Confirmed sensitization to beryllium as outlined in the guidance provides objective evidence establishing Be exposure—regardless of duration or amount. The guidance clarifies the criteria by which work-relatedness of such exposures must be evaluated.</li> </ol> <p>This comment also raises additional legitimate concerns—and we will coordinate with L&amp;I's Division of Occupational Safety and Health—but the guidance was not developed to address workplace monitoring and data sampling for the purposes of exposure prevention and workplace safety.</p> <ol style="list-style-type: none"> <li>2. Same response as to the first comment by Kris Tefft.</li> <li>3. Same response as to the first comment by Kris Tefft. Additional concerns expressed in this comment are beyond the scope of what the guidance was intended to address and we have insufficient information to comment on this.</li> <li>4. We do not have a position about how the medical director on site at Hanford makes decisions to have workers seek further medical evaluation. The guidance is only to summarize current literature and expert opinion about how to diagnose BeS and CBD.</li> </ol>
<p><b>Josh Artzer</b>, Richland, WA</p>	<p>Concurs with everything Calin Tebay stated. Reiterates there is no monitoring or sampling data available. DOE's response was adopting definition of “Beryllium <u>Associated</u> Workers.” Most workers would fall under the exception process, which creates issues with Penser.</p>	<p>Same response as above.</p>

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<p><b>Tim Takaro MD MPH MS,</b> Simon Fraser University</p>	<p><b>Makes 3 key points:</b></p> <ol style="list-style-type: none"> <li>1. States the “[beryllium] patch test cannot be recommended due to the possibility” of creating BeS.</li> <li>2. Recommends that three or more borderline blood BeLPTs also be used to diagnose BeS/CBD, stating that to do otherwise is “too strict for workers with a history of exposure to the hazard who have an interstitial lung condition (UIP or similar). In these cases...three or more borderline BeLPTs should enable a designation of CBD for administrative purposes.”</li> <li>3. <b>Administrative decision to call CBD with no positive BeLPT:</b> Recommends that when Usual Interstitial Pneumonia exists + strong exposure history, + absence of evidence for BeS: “an administrative decision may be required for a worker to be compensated in the absence of evidence of sensitization.”</li> </ol>	<ol style="list-style-type: none"> <li>1. The guidance document does not recommend or require the use of the beryllium skin patch test due to the risk of inducing sensitization to beryllium.</li> <li>2 and 3: Criterion 2c of the beryllium sensitization section of the guidance states that BeS is confirmed by at least three borderline blood BeLPTs, citing literature that determined the predictive value of three borderline results was higher than the minimum three result combination requiring one abnormal and one borderline blood BeLPT.</li> </ol> <p>Any guideline, guidance, or policy must incorporate the need to provide appropriate evidence-based quality care for the worker, while ensuring decisions are in keeping with Washington’s industrial insurance laws. Both the definition of definitive work-related CBD, and the four part test of the objective evidence required to diagnose CBD when a positive BeLPT is not present, are consistent with the 2014 American Thoracic Society (ATS) consensus statement on CBD*, acknowledging that “differing combinations of diagnostic criteria” can be used to diagnose CBD. This guidance provides the best evidence-based clinical criteria available to allow a provider to render a decision on a more-probable-than-not basis, supported by his or her best clinical judgment and the objective findings.</p>
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\* Balmes, J.R., Abraham, J.L., Dweik, R.A., Fireman, E., Fontenot, A.P., Maier, L.A., Muller-Quernheim, J., Ostiguy, G., Pepper, L.D., Saltini, C., Schuler, C.R., Takaro, T.K., and Wambach, P.F., *An official American Thoracic Society statement: diagnosis and management of beryllium sensitivity and chronic beryllium disease*. Am J Respir Crit Care Med, 2014. **190**(10): p. e34-59.