

LETTER OF MEDICAL NECESSITY

{fill with date ***}

Subscriber:

DOB:

Subscriber ID:

Dear Insurance Representative:

I am writing to request prior authorization for genetic testing at in-network benefit coverage for **Malignant Hyperthermia** genetic testing. The patient is being evaluated for Malignant Hyperthermia susceptibility due to their {personal history of *** and/or family history of ***}. Genetic testing in these circumstances is standard of care and is medically indicated for the reasons below as it will directly impact patient care.

Malignant Hyperthermia (MH) is a severe adverse reaction to commonly used anesthetics (halothane, sevoflurane, desflurane, enflurane, isoflurane) or to depolarizing muscle relaxants (succinylcholine) (Nelson and Flewelling N Engl J Med 309:416-418, 1983; Larach et al. Anesth Analg 110:498-507, 2010; Rosenberg et al. www.genereviews.org, 2010). In susceptible patients these agents may trigger uncontrolled muscle hypermetabolism. In almost all cases, the first manifestations of MH occur in the operating room. Death can result unless the patient is promptly treated (Larach et al. Anesthesiology 108:603-611, 2008).

Knowledge of susceptibility is the key factor to avoid the morbidity/mortality associated with MH. Susceptibility may be determined by either a muscle biopsy test (sometimes called the in vitro muscle contraction test) or by DNA testing. The muscle biopsy test is more sensitive than DNA testing, but is expensive, painful, and requires travel to one of the few biopsy centers. DNA testing is not as sensitive, but has the advantages of being relatively low cost and requiring no travel (blood specimens are transported to the testing labs). DNA testing has the further advantage that once the causative mutation is identified in a proband, then other family members can be tested much more easily than with the muscle biopsy test.

Avoidance of the triggering agents (listed above) appears to be an almost completely effective means of preventing MH. Although somewhat more expensive and more difficult to administer, alternative anesthetics are available for patients at risk for MH (Wappler Current Opinion in Anesthesiology 23(3): 417-422, 2010). It is recommended that medical alert bracelets or other alert devices be worn by susceptible individuals to aid emergency room personnel (Malignant Hyperthermia Association of the United States, 2013; mhaus.org).

Sodium dantrolene has been shown to be an effective antidote to the triggering agents and has dramatically reduced the number of deaths due to MH (Harrison Br J Anaesth 81:626-629, 1998; Anderson and Jones Anesthesiology 44(1):57-61, 1976). These days, most surgical suites in developed nations stock dantrolene. However, since non-fatal MH events are still often accompanied by significant morbidity (Larach et al. Anesth Analg 110:498-507, 2010), they should be avoided through the use of alternative anesthetics. Calcium channel blockers should not be given together with dantrolene because of the risk of life-threatening hyperkalemia (Rosenberg et al. www.genereviews.org, 2010).

Based on results from the literature, the full gene test is estimated to detect likely causative mutations in roughly 65% of ideal MH test candidates. {insert specifics on why candidate is ideal or justify testing non-ideal candidate}. No one else in the family has undergone genetic testing therefore, full gene sequencing of the *RYR1* gene is necessary.

OR

Since an *RYR1* gene mutation has already been identified in the family, site specific *RYR1* gene testing for the known familial variant is being pursued.

The date of service for this testing is ***.

The laboratory providing the genetic testing is ***, TAX ID ***.

The CPT code for the genetic testing is ***.

The diagnosis code is ***.

The test is being ordered by Dr. *** NPI # : ***.

Please contact me at *** if I can provide you with any additional information. Please inform me of the result of this request directly.

Sincerely,

Name, Credentials

Title

Institution