Coverage for Li-Fraumeni syndrome whole-body MRI

*[Insert policy info here]*

To Whom It May Concern:

This letter is written on behalf of [*patient name]* regarding the decision to deny coverage for whole-body MRI (wbMRI). Know that sufficient evidence exists that wbMRI is necessary for optimal care and should be covered.

Li-Fraumeni syndrome (LFS) is a rare, hereditary predisposition to cancer caused by a germline mutation in the *TP53* gene. Individuals with LFS are at increased risk to develop various cancers including sarcoma (soft-tissue and osteosarcoma), adrenocortical carcinoma, brain tumors, and early-onset breast cancers, as well as other types of cancers. In a recent study, 22% of individuals with LFS were diagnosed with cancer before 5 years of age and 41% by 18 years of age, with 4% developing a malignancy during the first year of life1.

Comprehensive cancer surveillance with wbMRI, brain MRI, comprehensive bloodwork, and abdominal sonogram is recommended for children to detect cancers at early stages when they are most treatable and offer the best survival outcomes. **Published studies have shown that wbMRI is key to early cancer detection in this population2. Whole body MRI has recently been included in eviCore’s PEDONC-2.2 Li Fraumeni Syndrome Screening policy for all patients utilizing CPT® 764983.**

In children and adolescents with LFS, osteosarcoma is the most common tumor (30%) followed by adrenocortical carcinoma (27%), brain tumors (25%) and soft tissue sarcoma (23%)2. wbMRI is the most effective screening option in this high-risk pediatric patient population because it provides a comprehensive examination of the whole-body with a single test and does not require ionizing radiation, which is a known cancer risk factor in this population.

**A recent meta-analysis of baseline wbMRI showed that the detection of cancers was highest in those younger than 18 years (31%) compared with those aged 18 to 40 years (16%) and those older than 40 years (18%)1.** In addition, a recent UK study detected malignant neoplasms in 14% of *TP53* mutation carriers at baseline wbMRI suggesting that the detection rate for new malignancies with wbMRI may be higher in some populations4. **A standardized wbMRI protocol has been proposed, and experts and consensus groups agree that there is clinical utility for wbMRI in early detection of tumors which has been demonstrated to improve patient outcomes by identifying tumors at their earliest and most curable stages5-10.** The ability to screen for multiple cancers with a single examination in patients with LFS not only reduces the number of individual imaging tests required, but also the number of patient visits to an imaging service, thereby reducing related costs11,12.

**Pre-symptomatic cancer surveillance has been found to be cost-effective for patients with germline *TP53* pathogenic variants** with a mean cost of $117,102 and 27 life years for surveillance with wbMRI compared to a mean cost of $46,496 and 23 life years for a non-surveillance approach13. When measured against the commonly accepted willingness-to-pay threshold of $100,000 per life-year gained by third-party insurers, **the surveillance strategy that includes wbMRI has a 98% probability of being the most cost-effective option for early cancer detection for individuals with LFS, and one that improves clinical outcomes13.**

The Li-Fraumeni Syndrome Association’s board of directors, along with its Medical Advisory Board of top LFS researchers and providers, have determined there is sufﬁcient evidence to recommend that, in addition to regular physical exams and other investigations, all patients diagnosed with Li-Fraumeni syndrome receive annual, rapid, whole-body MRI scans.

There is increasingly robust evidence demonstrating the reduction in cancer-related mortality and improved survival associated with wbMRI for LFS10. We believe the body of evidence demonstrating the feasibility of wbMRI to detect early resectable cancers in LFS patients is more than sufficient to support the coverage of wbMRI for [*patient name*]. The CPT code(s) used for billing are [*CPT code(s)*]. If you have any questions regarding this request or need further information please contact us at [*contact information*].

Sincerely,

[*Name*]

References

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