



ADMINISTRATIVE POLICY STATEMENT INDIANA MARKETPLACE PLANS

Original Issue Date	Next Annual Review	Effective Date
06/06/2013	06/15/2019	06/15/2018
Policy Name		Policy Number
Medical Necessity	Off Label, /La	8470



H. REFERENCES

1. U.S. Food and Drug Administration (FDA). Off-label and investigational use of marketed drugs, biologics, and medical devices. Available at: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm>
2. U.S. Food and Drug Administration (FDA). Orphan Product Designations and Approval Search. Available at: <http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm>.
3. U.S. Food and Drug Administration (FDA). Developing Orphan Products: FDA and Rare Disease Day. Last updated February 16, 2016. Available at: [http://www.fda.gov/ForConsumers/Consumer Updates/ucm107293.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107293.htm).
4. National Comprehensive Cancer Network®. NCC

