

## SOLARAZE

(diclopfenac sodium)

### RATIONALE FOR INCLUSION IN PA PROGRAM

## **Background**

Solaraze (diclofenac sodium) gel is a prescription medicine used on the skin for actinic keratoses. Actinic keratosis (AK), also called solar keratosis, which is a chronic (long-term) condition of the skin caused by a chemical reaction to ultraviolet (UV) rays. Actinic keratosis can be linked to the development of skin cancer (1).

# **Regulatory Status**

FDA-approved indications: Solaraze gel is indicated for the topical treatment of actinic keratoses (AK). Sun avoidance is indicated during therapy (1).

Safety and effectiveness of Solaraze in pediatric patients less than 18 years of age have not been established (1).

# **Summary**

Solaraze (diclofenac sodium) gel is a prescription medicine used on the skin for actinic keratoses. Actinic keratosis (AK), also called solar keratosis, which is a chronic (long-term) condition of the skin. It is caused by a chemical reaction to ultraviolet (UV) rays. AK can be linked to the development of skin cancer. Safety and effectiveness of Solaraze in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Solaraze while maintaining optimal therapeutic outcomes.

#### References

1. Solaraze [package Insert]. Melville, NY: PharmaDerm. May 2016.