STATE OF RHODE ISLAND
EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES
APPEALS OFFICE

[redacted]

v. Docket No. 26-4783

RI EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES

DECISION

I. INTRODUCTION

A telephonic hearing on the above-entitled matter was held on August 27, 2026, and the Appellant declined the option of a video hearing. This matter was initiated by [redacted] (Guardians) on behalf of minor child [redacted] (Appellant) to appeal a decision made by Rhode Island Medicaid to deny payment of Iwilfin medication. The Appellant argues that although her primary insurance Blue Cross is covering the $25,000 a month medication, she is seeking to have Medicaid cover the out-of-pocket monthly cost of $127.54. For the reasons discussed in more detail below, the Appellant's appeal is denied.

II. JURISDICTION

The Executive Office of Health and Human Services (EOHHS) is authorized and designated by R.I.G.L. §42-7.2-6.1 and EOHHS regulation 210-RICR-10-05-2 to be the entity responsible for appeals and hearings related to human services. The administrative hearing was held in accordance with the

Administrative Procedures Act (R.I.G.L. §42-35.1 et. seq.) and EOHHS regulation 210-RICR-10-05-2.

III. ISSUE

The issue is whether Medicaid's denial of coverage/payment of the Appellant's out-of-pocket cost for Iwilfin medication was properly denied in accordance with State and Federal regulations as set forth below.

IV. PARTIES AND EXHIBITS

Present for EOHHS was Dr. Jerry Fingerut, Director of Medicaid, and Collette Onyejekwe, Pharmacy Director. Neither submitted any documentary evidence.

The Appellant was represented by her Guardians, [redacted]. The Guardians provided the following into evidence:

- The Appellant's appeal along with supporting documents.

V. RELEVANT LAW/REGULATIONS

Per 210 RICR 50-10-3, children eligible for Medicaid under the Katie Becket provision receive the same scope of services generally available to children eligible on the basis of the MAGI standard, even if they receive fee-for-service coverage instead of being enrolled in a Rite Care plan. Per 210-RICR-30-05-2.11(A)(1), experimental procedures, except as required by Rhode Island State law, are not covered under the RIte Care program.

Section 1905(a)(30) of the Social Security Act mandates Medicaid coverage for routine patient costs associated with items and services furnished during a beneficiary's participation in a qualifying clinical trial, unless those items and services are the subject of the clinical trial, are provided solely for data collection, or would not otherwise be covered by Medicaid if the beneficiary was not in a trial.

VI. FINDINGS OF FACT

- The Appellant is a 15-year-old girl who has Medicaid coverage through the Katie Beckett program and has private health insurance with Blue Cross Blue Shield (BCBS).
- The Appellant was diagnosed with Osteosarcoma, a form of bone cancer, on June 6, 2024.
- In January 2026, the Appellant underwent a medical procedure that confirmed relapsed Osteosarcoma. She was put in a clinical trial for the treatment of relapsed cancers and prescribed Iwilfin.
- The initial request for coverage of Iwilfin was denied by Blue Cross Blue Shield of Rhode Island/ Prime Therapeutics on March 23, 2026, on the grounds that the submitted information did not demonstrate an approved condition or an approved dose from an accepted source. After the submission of three appeals, the last appeal occurring on June 15, 2026, and a final external review completed by Emperion MCN, BC/BS approved coverage of the medication.
- An out-of-pocket cost of $127.54 per month remains after BC/BS's payments.
- Medicaid has not provided any payment towards the cost of the medication.
- On July 9, 2026, an appeal was filed on behalf of the Appellant to dispute Medicaid's denial of payment for the Iwilfin medication.
- Iwilfin is not a covered prescription under the Appellant's fee-for-service Medicaid coverage.
- EOHHS Medicaid Director Dr. Fingerut testified that Federal law specifically section 1905(a)(30) of title XIX does not allow Medicaid funds to be used for any item that might be investigational or the subject of a clinical trial.

- According to the Guardian, Iwilfin is an "off-label medication that is used in the care of pediatric patients with rare cancers". The Guardian concedes that the medication is labeled experimental but is FDA approved.

VII. DISCUSSION

The Appellant has a diagnosis of osteosarcoma and was prescribed Iwilfin as a participant in a clinical trial for the treatment of relapsed cancers. The Guardians report that Blue Cross and Blue Shield is providing coverage for the medication and argue that Medicaid should cover the Appellant's remaining out-of-pocket expenses for the medication. EOHHS maintains that while Iwilfin is a prescription medication proven to reduce the risk of relapse in children with high-risk neuroblastoma, it is not a covered prescription under the Appellant's Katie Becket Medicaid coverage because it is not FDA approved, and is therefore considered experimental, for her medical condition. The Guardians concede that Iwilfin is an off-label experimental medication for the treatment of osteosarcoma but testify it is the only available tolerable intervention for the Appellant that could reduce the risk of relapse.

State Medicaid regulations clearly state that experimental procedures are not covered by Medicaid unless required by Rhode Island State law (210 RICR 30-05-2.11). The record lacks any evidence that coverage of Iwilfin for the treatment of osteosarcoma is required by state law. Federal Medicaid regulation, Section 1905(a)(30) of the Social Security Act, further dictates that an experimental medication furnished or prescribed during a Medicaid beneficiary's participation in a clinical trial is not covered by Medicaid if the medication is the subject of the clinical trial, or would not otherwise be covered by Medicaid if the beneficiary was not in a trial.

In summary, the record establishes that Iwilfin is the subject of a clinical trial the Appellant is participating in and is considered experimental treatment for the Appellant's medical condition.

VIII. CONCLUSION OF LAW

After careful review of the testimony and evidence presented at the Administrative Hearing, it is clear by a preponderance of evidence that:

1. Iwilfin was prescribed to the Appellant as part of a clinical trial.
2. Iwilfin is an experimental drug for treatment of osteosarcoma.
3. Experimental treatments are not a covered benefit under the Appellant's Medicaid coverage.

IX. DECISION

Based on the foregoing findings of fact, conclusions of law, evidence, and testimony, it is found that a final order be entered that there is sufficient evidence to support EOHHS' denial of the Appellant's request to cover her out-of-pocket costs for Iwilfin.

APPEAL DENIED

/s/ Velmont Richardson
Appeals Officer

NOTICE OF APPELLATE RIGHTS

This decision is a final order under R.I.G.L. § 42-35-12. Under R.I.G.L. § 42-35-15, this Order may be appealed to court within thirty (30) days of the mailing of this decision. Such appeal, if taken, must be completed by filing a complaint in court. The filing of the complaint

does not itself stay enforcement of this order. The agency may grant, or the reviewing court may order, a stay upon the appropriate terms.

Appeals are generally filed in the Providence County Superior Court. However, appeals affecting or concerning children under the age of eighteen (18) and/or appeals of a DCYF action may need to be filed in Providence Family Court. If you have any questions about which court a complaint for appeal should be made, you should seek the advice of an attorney, Rhode Island Legal Services, or the clerk of the court where you wish to file your appeal. The courts' contact information can be found on the judiciary's website (https://www.courts.ri.gov). Copies of the appeal must be served upon all parties in your case within ten (10) days of the filing of your appeal.

If you exercise any of these appellate rights, please inform the EOHHS appeals office of this so we can prepare a copy of the record for the court. You can contact the Appeals Office at OHHS.AppealsOffice@ohhs.ri.gov, 401.462.2132 (Phone), 401.462.0458 (Fax), or at 3 West Road, Virks Building, Cranston, RI 02920.

CERTIFICATION

I hereby certify that I mailed, via regular mail, postage prepaid, a true copy of the foregoing to [redacted]; copies were sent, via email, to the Appellant's Authorized Representative at [redacted] EOHHS Representatives Dr. Jerry Fingerut, Collete Onyejekwe, Jane Morgan, and Amy Hulberg on this 23rd day of September, 2026.

Rebecca L. Allen