

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR

**ACTION REFERRAL**

TO <i>Myus</i>	DATE <i>5/14/09</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER  <div style="text-align: right; font-size: 1.2em;">1011542</div>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR  <div style="text-align: center;"> <i>Ci Emma Steiner</i>  </div>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>5/26/09</i> DATE DUE _____  <input type="checkbox"/> Necessary Action

Cleared 5/14/09, letter attached.

APPROVALS <small>(Only when prepared for director's signature)</small>	APPROVE	* DISAPPROVE <small>(Note reason for disapproval and return to preparer.)</small>	COMMENT
1.			
2.			
3.			
4.			



# The Children's Hospital of Philadelphia®

Division of Oncology

34th Street and  
Civic Center Boulevard  
Philadelphia, Pa. 19104-4399

215-590-2810  
Fax 215-590-4183

**RECEIVED**

MAY 14 2009

Department of Health & Human Services  
OFFICE OF THE DIRECTOR

RE: ALANA BRYAN  
MRN: 5512878  
DOB: 02/04/08

May 11, 2009

## LETTER OF MEDICAL NECESSITY

To Whom It May Concern:

Alana was diagnosed with acute lymphoblastic leukemia in August 2008 at the age of 7 months. She presented with pallor, petechiae and irritability and her initial CBC showed a white blood cell count of 21,000, hemoglobin 4.4, and platelet count of 5000. Bone marrow aspirate confirmed the diagnosis of acute lymphoblastic leukemia. Central nervous system was negative for blasts. Based upon flow cytometry studies, her age, and cytogenetics, she was diagnosed with MLL-positive infant leukemia, one of the most challenging types of ALL to treat and cure.

Alana started therapy in South Carolina but transferred to the Children's Hospital of Philadelphia (CHOP) in the first month of therapy so that she could be enrolled in a Children's Oncology Group trial (AALL0631) and receive a promising new drug for infant ALL (CEP-701). She did enter remission with intensive induction and intensification chemotherapy and, overall, had a typical course for an infant with ALL. Infant therapy is complicated by the patient's size, the immature immune system, and an increased dependence upon hospital based supportive care.

After receiving 6 months of intensive therapy at CHOP, the majority of which she was inpatient, we permitted Alana to get several weeks of outpatient chemotherapy (Continuation Phase) at the hospital where she was diagnosed. She remained on the COG study and all data reporting was done by CHOP, with information provided by her oncologist in Greenville. Unfortunately, on 3/13/09 she had a bone marrow relapse while she was receiving continuation chemotherapy back in South Carolina. After much discussion between the family, the doctors in Greenville, and myself, it was decided to start her on a relapsed ALL protocol based upon a published clinical trial done here at CHOP. As is typical with relapsed ALL therapy, confounded by her age, she had several severe complications since her relapse therapy, including a GI bleed and typhilitis. Due to these complications she was transferred from Greenville to MUSC. The family had requested transfer back to CHOP at that time but it was denied. I have been in communication with her oncologists at both Greenville and MUSC throughout.

The prognosis for patients with infant leukemia is poor to start and relapse on therapy has a dismal prognosis. Fewer than 5% will be disease-free survivors without allogeneic hematopoietic stem cell transplant. Infants should be transplanted at experienced pediatric transplant centers that routinely transplant infants due to their complex medical problems and increased risk for infections. We are requesting permission for Alana to receive her transplant at the Children's Hospital of Philadelphia, which has significant infant and cord blood transplant experience. CHOP is one of the largest pediatric blood and marrow transplant centers in the US, and we have FACT accreditation for clinical, collection and stem cell laboratory. We transplant over 30 patients with allogeneic donors per year and have extensive experience in both unrelated donors and unrelated cord blood transplants. Given the complexity of an





*State of South Carolina*  
*Department of Health and Human Services*

Mark Sanford  
Governor

Emma Forkner  
Director

May 19, 2009

Susan R. Rheingold, MD  
Medical Director, Oncology Outpatient Program  
The Children's Hospital of Philadelphia  
34<sup>th</sup> Street and Civic Center Boulevard  
Philadelphia, PA 19104-4399

Re: Alana Bryan

Dear Dr. Rheingold:

Thank you for corresponding regarding this Medicaid beneficiary. My understanding is that the parents have appealed a previous South Carolina Department of Health and Human Services (SC DHHS) decision related to this matter and I am not aware of the outcome of this appeal.

The South Carolina Medicaid program and its parent agency SC DHHS has long-standing guidance relating to payment for medical care of its beneficiaries that relate to out-of-state services. Specifically, if the clinical care is available in the state of South Carolina and that care is comparable to care that is rendered elsewhere, the program cannot support out-of-state transport and services. If comparable care is not available in South Carolina, the SC DHHS works with a number of out-of-state institutions to assure that its beneficiaries do receive appropriate services.

Thank you for your advocacy regarding this patient and for the overview of your excellent oncology outpatient program at the Children's Hospital of Philadelphia.

Sincerely,

A handwritten signature in cursive script, appearing to read "Marion Burton".

O. Marion Burton, MD  
Medical Director

#642  
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