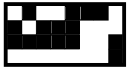


PEDS-C THERAPY STOP/RESTART FORM

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47353

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	
<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<input type="radio"/> Correction
	mm dd			
		yyyy		

Instructions:

Use this form for all therapy groups to report therapy stops and restarts. Report the date therapy was first started on the Baseline Assessment.

PEG 2A STOPPED

	Yes	No		
1. Has the patient's Peg2a therapy been stopped?	<input type="radio"/>	<input type="radio"/>	CRA Use Only	
If No , skip to item 5.				
2. Date Peg2a therapy stopped:	<input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 40px; height: 20px;" type="text"/>			
	mm	dd		yyyy
3. Type of stop (choose one item):	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>
	Temporary	Permanent		Undetermined
4. Reason(s) for stop (Answer each item):	Yes	No		
A. Parent withdrew consent:	<input type="radio"/>	<input type="radio"/>		
B. Patient withdrew consent:	<input type="radio"/>	<input type="radio"/>		
C. Positive serum or urine pregnancy test (patient):	<input type="radio"/>	<input type="radio"/>		
D. Male patient's sexual partner pregnant:	<input type="radio"/>	<input type="radio"/>		
E. Evidence of severe retinopathy:	<input type="radio"/>	<input type="radio"/>		
F. Patient hospitalized:	<input type="radio"/>	<input type="radio"/>		
G. Concurrent medical condition:	<input type="radio"/>	<input type="radio"/>		
H. Serious adverse event:	<input type="radio"/>	<input type="radio"/>		
I. Major, unresponsive depression:	<input type="radio"/>	<input type="radio"/>		
J. Absolute neutrophil count < 250 or febrile neutropenia	<input type="radio"/>	<input type="radio"/>		
K. Platelet count < 25,000	<input type="radio"/>	<input type="radio"/>		
L. Life threatening toxicity	<input type="radio"/>	<input type="radio"/>		
M. Hemoglobin < 8.5 gm/dl	<input type="radio"/>	<input type="radio"/>		
N. Indirect bilirubin > 5 mg/dl	<input type="radio"/>	<input type="radio"/>		
O. Indirect bilirubin > 5 mg/dl for > 4 weeks	<input type="radio"/>	<input type="radio"/>		
P. End of therapy per Protocol	<input type="radio"/>	<input type="radio"/>	stppegprotend	
Q. Other	<input type="radio"/>	<input type="radio"/>		
Specify: _____				

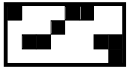
Please continue to page 2.

Signature: _____

Certif. #: -

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Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	
<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> / <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> / <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	<input type="radio"/> Correction
	mm dd yyyy			

<p>PEG 2A RE-START</p> <p>5. Has the patient's Peg2a therapy been restarted? Yes No <input type="radio"/> <input type="radio"/></p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin-left: 20px;"> If No, skip to item 8. </div> <p>6. Restart dose: <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> mcg</p> <p>7. Date Peg2a therapy restart: <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> / <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> / <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> mm dd yyyy</p> <hr/> <p>RV/PLACEBO STOPPED</p> <p>8. Has the patient's RV/placebo therapy been stopped? Yes No <input type="radio"/> <input type="radio"/></p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin-left: 20px;"> If No, skip to item 12. </div> <p>9. Date RV/placebo therapy stopped: <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> / <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> / <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> mm dd yyyy</p> <p>10. Type of stop (choose one item): <input type="radio"/> Temporary <input type="radio"/> Permanent <input type="radio"/> Undetermined </p> <p>11. Reason(s) for stop (Answer each item):</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 45%;"></td> <td style="width: 5%; text-align: center;">Yes</td> <td style="width: 5%; text-align: center;">No</td> </tr> <tr> <td>A. Parent withdrew consent:</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>B. Patient withdrew consent:</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>C. Positive serum or urine pregnancy test (patient):</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>D. Male patient's sexual partner pregnant:</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>E. Evidence of severe retinopathy:</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>F. Patient hospitalized:</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>G. Concurrent medical condition:</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>H. Serious adverse event:</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>I. Major, unresponsive depression:</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>J. Absolute neutrophil count < 250 or febrile neutropenia</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>K. Platelet count < 25,000</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>L. Life threatening toxicity</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>M. Hemoglobin < 8.5 gm/dl</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>N. Indirect bilirubin > 5 mg/dl</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>O. Indirect bilirubin > 5 mg/dl for > 4 weeks</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> <tr> <td>P. End of therapy per Protocol</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/> <i>stprvprotend</i></td> </tr> <tr> <td>Q. Other</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;"><input type="radio"/></td> </tr> </table> <p style="margin-left: 20px;">Specify: _____</p>		Yes	No	A. Parent withdrew consent:	<input type="radio"/>	<input type="radio"/>	B. Patient withdrew consent:	<input type="radio"/>	<input type="radio"/>	C. Positive serum or urine pregnancy test (patient):	<input type="radio"/>	<input type="radio"/>	D. Male patient's sexual partner pregnant:	<input type="radio"/>	<input type="radio"/>	E. Evidence of severe retinopathy:	<input type="radio"/>	<input type="radio"/>	F. Patient hospitalized:	<input type="radio"/>	<input type="radio"/>	G. Concurrent medical condition:	<input type="radio"/>	<input type="radio"/>	H. 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Please continue to page 3.

Signature: _____ Certif. #: -

PEDS-C THERAPY STOP/RESTART FORM

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Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	<input type="checkbox"/> Correction
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mm dd yyyy	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	

RV/PLACEBO RESTART

12. Has the patient's RV/placebo therapy been restarted?

Yes No

If **No**, skip to Signature and Certif. #.

13. Restart dose of RV/placebo:

A. In AM:

mg

B. In PM:

mg

14. Date therapy restart:

/ /
mm dd yyyy

CRA Use
Only

Signature: _____

Certif. #: -