

PEDS-C THERAPY STOP/RESTART FORM

PDC 38
Rev 0
01/04/2005
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11012

Please Use Black Pen To Fill Out Form.

Week # <i>week</i>	Date of Assessment <i>assessdt</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	Corrfix 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

1. Has the patient's Peg2a therapy been stopped?

Yes	No
<input type="radio"/>	<input checked="" type="radio"/> <i>stpeg</i>

If **No**, skip to item 5.

2. Date Peg2a therapy stopped:

<i>stpegdt</i>	/	/
mm	dd	yyyy

3. Type of stop (choose one item):

Temporary	Permanent	Undetermined
<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/> <i>stpegtyp</i>

4. Reason(s) for stop (Answer each item):

A. Parent withdrew consent:

Yes	No
<input type="radio"/>	<input checked="" type="radio"/> <i>stpegwdprt</i>

B. Patient withdrew consent:

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegwdpat</i>
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C. Positive serum or urine pregnancy test (patient):

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegpreg</i>
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D. Male patient's sexual partner pregnant:

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegmalpreg</i>
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E. Evidence of severe retinopathy:

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegtrno</i>
-----------------------	---

F. Patient hospitalized:

<input type="radio"/>	<input checked="" type="radio"/> <i>stpeghosp</i>
-----------------------	---

G. Concurrent medical condition:

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegmedcon</i>
-----------------------	---

H. Serious adverse event:

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegsae</i>
-----------------------	--

I. Major, unresponsive depression:

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegdep</i>
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J. Absolute neutrophil count < 250 or febrile neutropenia

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegneutro</i>
-----------------------	---

K. Platelet count < 25,000

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegplat</i>
-----------------------	---

L. Life threatening toxicity

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegtox</i>
-----------------------	--

M. Hemoglobin < 8.5 gm/dl

<input type="radio"/>	<input checked="" type="radio"/> <i>stpeghgb</i>
-----------------------	--

N. Indirect bilirubin > 5 mg/dl

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegbili5</i>
-----------------------	--

O. Indirect bilirubin > 5 mg/dl for > 4 weeks

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegbili5gt4</i>
-----------------------	---

P. Other

<input type="radio"/>	<input checked="" type="radio"/> <i>stpegothr</i>
-----------------------	---

Specify: _____

CRA Use
Only

Please continue to page 2.

Signature: _____

Certif. #: *staffid1* -

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Week # <i>week</i>	Date of Assessment <i>assessdt</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	corrfix Correction
[][]	[][] / [][] / [][][][] <small>mm dd yyyy</small>	[][] - [][][][] - [][]	[][][][]	

PEG 2A RE-START

5. Has the patient's Peg2a therapy been restarted?

Yes	No
<input type="radio"/>	<input type="radio"/> <i>rstpeg</i>

If **No**, skip to item 8.

6. Restart dose:

<i>rstpegdos</i>	mcg
[][][]	

7. Date Peg2a therapy restart:

<i>rstpegdt</i>	/	[][]	/	[][][][]
<small>mm</small>		<small>dd</small>		<small>yyyy</small>

CRA Use
Only

RV/PLACEBO STOPPED

8. Has the patient's RV/placebo therapy been stopped?

Yes	No
<input type="radio"/>	<input type="radio"/> <i>stprv</i>

If **No**, skip to item 12.

9. Date RV/placebo therapy stopped:

<i>stprvdt</i>	/	[][]	/	[][][][]
<small>mm</small>		<small>dd</small>		<small>yyyy</small>

10. Type of stop (choose one item):

<input type="radio"/> Temporary	<input type="radio"/> Permanent	<input type="radio"/> Undetermined
<i>stprvtyp</i>		

11. Reason(s) for stop (Answer each item):

- A. Parent withdrew consent:
- B. Patient withdrew consent:
- C. Positive serum or urine pregnancy test (patient):
- D. Male patient's sexual partner pregnant:
- E. Evidence of severe retinopathy:
- F. Patient hospitalized:
- G. Concurrent medical condition:
- H. Serious adverse event:
- I. Major, unresponsive depression:
- J. Absolute neutrophil count < 250 or febrile neutropenia
- K. Platelet count < 25,000
- L. Life threatening toxicity
- M. Hemoglobin < 8.5 gm/dl
- N. Indirect bilirubin > 5 mg/dl
- O. Indirect bilirubin > 5 mg/dl for > 4 weeks
- P. Other

Yes	No
<input type="radio"/>	<input type="radio"/> <i>stprvwdprt</i>
<input type="radio"/>	<input type="radio"/> <i>stprvwdpat</i>
<input type="radio"/>	<input type="radio"/> <i>stprvpreg</i>
<input type="radio"/>	<input type="radio"/> <i>stprvmalpreg</i>
<input type="radio"/>	<input type="radio"/> <i>stprvrtno</i>
<input type="radio"/>	<input type="radio"/> <i>stprvhosp</i>
<input type="radio"/>	<input type="radio"/> <i>stprvmedcon</i>
<input type="radio"/>	<input type="radio"/> <i>stprvsae</i>
<input type="radio"/>	<input type="radio"/> <i>stprvdep</i>
<input type="radio"/>	<input type="radio"/> <i>stprvneutro</i>
<input type="radio"/>	<input type="radio"/> <i>stprvplat</i>
<input type="radio"/>	<input type="radio"/> <i>stprvtox</i>
<input type="radio"/>	<input type="radio"/> <i>stprvhgb</i>
<input type="radio"/>	<input type="radio"/> <i>stprvbili5</i>
<input type="radio"/>	<input type="radio"/> <i>stprvbili5gt4</i>
<input type="radio"/>	<input type="radio"/> <i>stprvothr</i>

Specify: _____

Please continue to page 3.

Signature: _____

Certif. #: _____

<i>staffid2</i>	-	[][][]
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mm	dd / yyyy	- - -		

RV/PLACEBO RESTART

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

Yes No
 rstrv

CRA Use
Only

If No, skip to Signature and Certif. #.

13. Restart dose of RV/placebo:

A. In AM:

rstrvdosam mg

B. In PM:

rstrvdospm mg

14. Date therapy restart:

rstrvdt / /

Signature: _____

Certif. #:

staffid3 -