

1. Reporter Details		<input type="checkbox"/> Initial	<input type="checkbox"/> Follow-up
Reporter Name:		E-mail:	
Contact address:		Telephone number:	
		Fax number:	
Type:	<input type="checkbox"/> Physician (Specialty): _____	<input type="checkbox"/> Consumer or other non healthcare professional	
	<input type="checkbox"/> Pharmacist	<input type="checkbox"/> Other (Specify) _____	
If reporter is a consumer, have they informed their physician of the exposure?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Has the consumer provided permission to contact their healthcare professional?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please provide healthcare professional contact details:			
Name:		Type:	Telephone:
Address:		Email:	

2. Patient Details			
Date of birth (Day/Month/Year)	Age Yrs/mo.	Height cm	Weight kg

3. Company Drug Section									
	Name	Strength	Dose	Route	Indication	Treatment start date (day/month/year)	Treatment end date (day/month/year)	Lot	Expiry
1.									
2.									
3.									

4. Details of Adverse Event			
Adverse Event	Start Date	Stop Date	Outcome
			<input type="checkbox"/> Recovered / Resolved <input type="checkbox"/> Recovered / Resolved With Sequelae <input type="checkbox"/> Recovering /Resolving <input type="checkbox"/> Not Recovered /Not Resolved <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown

5. Medical History	
Medical History <i>(Enter all treatments below)</i>	<ul style="list-style-type: none"> ▪ IBD History Specify Type Date of Diagnosis Therapies Received ▪ Malignancy Specify Type Date of Diagnosis ▪ Immune Deficiency Human Immunodeficiency Virus (+/-) If (+), Date of Diagnosis

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	If (+), CD4 Count (at time of PML diagnosis)
Prior Treatments for IBD:	<ul style="list-style-type: none"> ▪ Ongoing graft-versus-host disease (Yes/No) ▪ Long-term immunosuppression (ie. greater than 8 weeks) (Yes/No) Include medications, dose, route, frequency, start/stop dates for each medication/treatment received.
Prior Treatments for Other Important Past Medical History Conditions:	

6. PML Disease

Signs and Symptoms of PML *(include onset date(s) for each sign and symptoms)*

Neurology Examinations *(include date examination was conducted and results of examination)*

Brain MRI / Brain Imaging Studies *(include date of MRI and MRI results, types and results of other brain imaging studies)*

Lumbar Puncture Results *(document all lumbar punctures, especially date of lumbar puncture of the first JCV DNA (+) cerebrospinal fluid (CSF) result)*

Brain Biopsy *(include date of brain biopsy, highlights of brain biopsy pathology report, evidence of JCV on immunohistochemistry or FISH staining)*

7. Labs

	Date (day/month/year)	Results	Normal Range
White Blood Cell Count			
White Blood Cell Count Differential			
Hemoglobin			
Hematocrit			
Platelet Count			
Other			
JCV Antibody Status			

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JCV DNA (non-CSF sources for JCV testing)			
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8. PML Diagnosis and Treatment

Date of PML Diagnosis (day/month/year)	Plasma Exchange (PLEX) / Immunoabsorption (IA) <input type="checkbox"/> PLEX <input type="checkbox"/> IA Dates of treatment: Number of cycles:	Other PML Treatments (<i>include type of treatment(s), dose, route, frequency, start/stop dates for each treatment received</i>)
Date of Permanent Discontinuation of Teriflunomide Treatment (day/month/year)		

9. Follow-Up

Any treatments for underlying disease post-PML diagnosis: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, specify:
PML Outcome: Event of PML continuing: <input type="checkbox"/> Yes <input type="checkbox"/> No Current clinical status of patient: Outcome of the event: <input type="checkbox"/> Recovered / Resolved <input type="checkbox"/> Recovered / Resolved With Sequelae <input type="checkbox"/> Recovering /Resolving <input type="checkbox"/> Not Recovered /Not Resolved <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown If PML resulted in fatal outcome, provide date of death (day/month/year): Cause of death: Autopsy conducted (and report available): <input type="checkbox"/> Yes <input type="checkbox"/> No

10. Completed By

Name:	Signature:	Date (day/month/year):

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