

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	ALFA INTERFERONS	
BRAND NAME	INTRON A	
	INTRON A W/ DILUENT	
(generic)	(interferon alfa-2b)	
Status: CVS/caremark Criteria		MDC
Type: Initial Prior Authorization		Ref # 555-A

FDA-APPROVED INDICATIONS¹

- AIDS-related Kaposi's sarcoma
- Chronic hepatitis B virus infection
- Chronic hepatitis C virus infection
- Condylomata acuminata
- Follicular non-Hodgkin's lymphoma
- Hairy cell leukemia
- Malignant melanoma

Compendia Uses

- Giant cell tumor of the bone²
- Chronic myelogenous leukemia (CML)²⁻⁴
- Renal cell carcinoma (RCC)²⁻⁴
- Systemic light chain amyloidosis²
- Adult T-cell leukemia/lymphoma (ATLL)²
- Mycosis Fungoides (MF)/Sezary syndrome (SS)²⁻⁴
- Desmoid tumors (soft tissue sarcoma)²
- Polycythemia vera^{3,5}
- Acute hepatitis C virus infection^{3,4}

CRITERIA FOR APPROVAL

1	Is Intron-A prescribed for the treatment of any of the following diagnoses: 1) Adult T-cell leukemia/lymphoma, 2) AIDS-related Kaposi sarcoma, 3) Desmoid tumors (soft tissue sarcoma), 4) Follicular non-Hodgkin's lymphoma, 5) Giant cell tumor of the bone, 6) Hairy-cell leukemia, 7) Mycosis fungoides or Sezary syndrome, 8) Polycythemia vera, OR 9) Systemic light chain amyloidosis. 10) Melanoma, 11) Renal cell carcinoma? [If yes, no further questions.]	Yes	No
2	Is Intron-A prescribed for the treatment of any of the following diagnoses: 1) Chronic hepatitis C virus infection, 2) Chronic hepatitis B virus infection, OR 3) Acute hepatitis C virus infection? [If yes, no further questions.]	Yes	No
3	Is Intron-A prescribed for treatment of condylomata acuminata (genital warts) and the patient is not a candidate for one standard treatment option (e.g., podofilox, imiquimod, cryotherapy, podophyllin resin) [If yes, no further questions.]	Yes	No
4	Is Intron-A prescribed for treatment of chronic myelogenous leukemia (CML) and meet either of the following criteria: 1) Patient is unable to tolerate tyrosine kinase inhibitor(s) OR	Yes	No

2) Patient is post hematopoietic stem cell transplant?

Guidelines for Approval					
Duration of Approval	12 months	Duration of Approval	48 weeks	Duration of Approval	12 months
Set 1: ATLL, AIDS-related Kaposi sarcoma, desmoid tumors, FL, GCTB, hairy-cell leukemia, MF/SS, polycythemia vera, systemic light chain amyloidosis, melanoma, RCC		Set 2: Chronic Hep C, Chronic Hep B, Acute Hep C		Set 3: Condylomata acuminata	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	None	2	1	3	1
					2
Duration of Approval	12 months	Duration of Approval	12 months	Duration of Approval	12 months
Set 4: CML					
Yes to question(s)	No to question(s)				
4	1				
	2				
	3				

Internal Use Only – Mapping Instructions		
	Yes	No
1.	Approve, 12 months	Go to 2
2.	Approve, 48 weeks	Go to 3
3.	Approve, 12 months	Go to 4
4.	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare-approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Intron A [package insert]. Whitehouse Station, NJ: Schering Corporation; February 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2015 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed April 01, 2016.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed April 01, 2016.
4. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. April 01, 2016.
5. CVS Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Hematology-Oncology Clinical Programs. September 12, 2012.

DOCUMENT HISTORY

Written: UM Development (LS) 07/1998
 Revised: LS 04/1999, 03/2001, 08/2001 JG 02/2002, 11/2002, 01/2004; TM 11/2004, 03/2005, 05/2005; NB 07/2006(3);



Specialty Clinical Development (MG) 06/2007; 08/2008; GY 11/2009; AC 09/2010, 10/2011 (CMS); KH 12/2011; AC 09/2012 (CMS); HY 01/2013, 09/2013 (CMS), LD 05/2013, ST 03/2014, 09/2014 (CMS); JP 03/2015; ST 08/2015 (CMS); PK 04/2016 (removed "up to" per prior year CMS comment); JP 06/2016 (CMS), PK 07/2017

Reviewed:

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External Review:

05/2002; 02/2003; 02/2004; 11/2005; 12/2006, 09/2007, 12/2008, 12/2009, 12/2010, 02/2012, 09/2012, 03/2013, 07/2013, 07/2014, 06/2015, 06/2016