

**Accountable Action Summary: Patient Care Plan Template
Adalimumab (HUMIRA)**

Boxed Warning Summary	Physician Actions	Nursing Actions	Pharmacy Action	Patient Actions	Facility Actions/Other/Comments
Risk of Infection					
<ul style="list-style-type: none"> Increased risk of serious and sometimes fatal infections including TB, bacterial sepsis, invasive fungal infections, and other opportunistic infections during therapy. 	<ul style="list-style-type: none"> Evaluate the risk and benefit of initiating therapy in patients with a) chronic or recurrent infections; b) exposure to TB; c) history of opportunistic infection; d) resided/travelled in areas of endemic TB or endemic mycoses (e.g., histoplasmosis, coccidioimycosis, blastomycosis); e) underlying conditions that predispose to infection. Treatment should not be initiated in patients with active infection, including localized infection Test patient for latent TB before initiating and periodically during therapy Initiate treatment for latent TB before use of therapy. Consider anti-TB therapy before initiation of adalimumab in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed or for patients with a negative test but having risk factors for TB infection. Discontinue if patient develops serious infection or sepsis. Initiate prompt diagnostic workup for an immunocompromised 	<ul style="list-style-type: none"> Monitor patients for signs and symptoms of infection during and after treatment, including possible development of TB in patients who tested negative for latent TB prior to therapy. Tests for latent TB infection may be falsely negative while on adalimumab therapy. Closely monitor for signs and symptoms of active HBV infection. 	<ul style="list-style-type: none"> Monitor patients who are concomitantly taking immunosuppressants such as methotrexate or corticosteroids for these individuals may present more frequently with disseminated and sometimes fatal infections Identify patients on abatacept or anakinra therapy. Concomitant use with TNF-blocker is not recommended as these RA patients are associated with a higher risk of serious infections. Screen med profile for other biologic products. Avoid concurrent use. Screen vaccine orders. Patients may receive concurrent vaccinations except for live vaccines 	<ul style="list-style-type: none"> Report any signs and symptoms of recent or current infection to physician Report any past or current infections, including but not limited to fungal disease, or TB, HBV. Report recent travel to areas outside of the U.S. or in U.S. areas at risk of increased fungal infections (Ohio or Mississippi River valleys) 	<ul style="list-style-type: none"> Develop order set which identifies patients at risk for infection and prompts testing for TB. Induration of 5 mm or greater with tuberculin skin test should be considered positive result when assessing if treatment for latent tuberculosis is needed prior to initiating therapy.

	<p>patient. Initiate appropriate antimicrobial treatment.</p> <ul style="list-style-type: none"> • Empiric antifungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness • Evaluate patients at risk of HBV or HBV reactivation. • Use caution in prescribing TNF blockers in HBV carriers. Closely monitor for reactivation of HBV infection during and for several months post therapy. 				
Malignancy in Children and Adolescents					
<ul style="list-style-type: none"> • Lymphoma and other malignancies have been reported with TNF-blockers • Reports of aggressive and fatal HSTCL have occurred in patients treated with TNF blockers, including adalimumab. 	<ul style="list-style-type: none"> • Evaluate risk and benefit of initiating therapy in patients with known malignancy (other than NMSC) or when considering to continue a TNF-blocker in patients who develop a malignancy 	<ul style="list-style-type: none"> • Verify whether patient has any malignancy (patient history and assessment) 	<ul style="list-style-type: none"> • Verify whether patient has any malignancy via medication history • Identify patients receiving treatment with azathioprine or 6-mercaptopurine concurrently with TNF blocker at or prior to diagnosis. Almost all cases of HSTCL have occurred in have occurred in patients with Crohn's disease or ulcerative colitis and in adolescent and young adult males. Almost all were receiving concurrent therapy with these agents 	<ul style="list-style-type: none"> • Report past history of malignancy 	
<u>REMS Summary Medication Guide Communication Plan</u>	<i>Physician Actions</i>	<i>Nursing Actions</i>	<i>Pharmacy Action</i>	<i>Patient Actions</i>	<i>Facility Actions/Other/Comments</i>
<ul style="list-style-type: none"> • Alert/warn HCPs about unrecognized histoplasmosis and other 	<ul style="list-style-type: none"> • Counsel patient regarding serious safety issues as outlined in med guide; 		<ul style="list-style-type: none"> • Counsel patient regarding safety issues as outlined in med 	<ul style="list-style-type: none"> • Read med guide • Report any signs and symptoms of 	<ul style="list-style-type: none"> • Med Guide

<p>invasive fungal infections associated with TNF blockers.</p> <ul style="list-style-type: none"> • Educating patients about the serious risks associated with therapy • Med Guide dispensed with each prescription (not inpatient specific) 21 CFR 208.24 	<p>risks of use and signs and symptoms of infection</p>		<p>guide: risks of use and signs and symptoms of infection</p> <ul style="list-style-type: none"> • Dispense med guide with each prescription. • Inpatient dispensing of Med Guide not specified. 	<p>recent or current infection to physician</p> <ul style="list-style-type: none"> • Report any past or current infections, including but not limited to fungal disease, or TB, HBV. • Report recent travel to areas outside of the U.S. or in U.S. areas at risk of increased fungal infections (Ohio or Mississippi River valleys) • Contact physician if signs or symptoms of infection occur 	
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Rev 5/11 *These actions are suggested. This template does not represent a standard of care nor is it a comprehensive description of the risks associated with the use of this drug. Healthcare providers must read the boxed warning and accompanying [full prescribing information](#) for a complete description of these risks and their management.*

Abbreviations:

HBV=Hepatitis B virus

HCP = healthcare provider

HSTCL = hepatosplenic T-cell lymphoma

NMSC=non-melanoma skin cancer

FDA Safety Information:

- [REMS Summary: Medication Guide, Communication Plan](#)
- [Information on TNF Blockers](#)
- [Safety Review update on reports of Hepatosplenic T-Cell Lymphoma in adolescents and young adults receiving TNF blockers, azathioprine and/or mercaptopurine \(April 2011\)](#)
- [Revised Boxed Warnings Planned per FDA Safety Review: Increased Risk of Lymphomas and Other Malignancies in Children/Adolescents Treated with TNF Blockers \(August 2009\)](#)
- [Revised Boxed Warning: TNF Blockers \(November 2009\)](#)

Link to www.blackboxrx.com for more information regarding boxed warning with this drug: [Adalimumab](#)

